

WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT THE OPIOID ABUSE EPIDEMIC?

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS

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FRIDAY, MAY 1, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:00 a.m., in room 2322, Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, McKinley, Burgess, Griffith, Bucshon, Flores, Brooks, Mullin, Collins, Upton (ex officio), DeGette, Schakowsky, Tonko, Clarke, Kennedy, Green, and Pallone (ex officio).

Staff present: Noelle Clemente, Press Secretary; Jessica Donlon, Counsel, Oversight and Investigations; Brittany Havens, Oversight Associate, Oversight and Investigations; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; Christopher Knauer, Democratic Oversight Staff Director; and Una Lee, Democratic Chief Oversight Counsel.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Well, good morning. Welcome here to the Oversight and Investigations Subcommittee hearing.

I just want to say it's Mental Health Month, so it's fitting that we are here today on this issue. This is the third in a series of hearings examining the growing problem of prescription drugs and heroin addiction that is ravaging our country. This is our Nation's single biggest public health concern.

Over the past 5 weeks, this subcommittee has heard from addiction experts working with local communities and our leading academic and research centers. Dr. Robert DuPont, the former White House Chief of Drug Control Policy and the first director of the National Institute on Drug Abuse, testified that Federal programs lack direction and standards on treating addiction as a chronic condition, and noted what is being done to follow up with patients to prevent relapses and put them on a path of real recovery? He challenged us to even ask the most fundamental question, "What is recovery?"

Dr. Anna Lembke of Stanford Medical School provided critical testimony on how we must revise our healthcare quality measures

to reduce overprescribing, reform medical privacy regulations, and incentivize the use of prescription drug monitoring programs.

We know that those with opiate addiction disorders need a broad range of treatment options and that many with substance abuse disorders have co-occurring psychiatric disorders, but we need to tear down Federal policy and funding barriers that keep us from treating both simultaneously.

About 3 weeks ago, one of today's witnesses, Mr. Michael Botticelli, the Director of the Office of National Drug Control Policy, presented a slide—I'm going to show it here—at the National Rx Summit on major causes of death from injury from 1999 to 2013. Quite a revealing slide. While the trends of other major causes of death, such as auto accidents went down, drug poisoning continued to go up 21 percent from 2008 till 2013. In many States, these numbers are soaring at high double-digit rate increases. As Mr. Botticelli has indicated to me privately and at the Rx Summit, we must do better, and we have much work to do.

Today, we will hear from Federal agencies charged with providing guidance, direction, and leadership in our Nation's public health response to the opiate epidemic. No Federal agency is more central in this ongoing epidemic than the Department of Health and Human Services or HHS. HHS and its Substance Abuse and Mental Health Services Administration, also known as SAMHSA, are responsible for leading our Nation's public health response to the opiate heroin abuse and addiction crisis.

SAMHSA regulates our country's 1,300 opiate treatment programs, and SAMHSA is responsible for certifying the 26,000 physicians who prescribe the most commonly used opiate maintenance medication, buprenorphine. According to testimony provided by SAMHSA before this subcommittee in April of last year, there were nearly 1.5 million people treated with these opiate maintenance medications in 2012, which is a fivefold increase in the last 10 years.

Has SAMHSA defined the goal of recovery for what these federally subsidized treatment programs are supposed to accomplish? Is SAMHSA collecting and evaluating meaningful data at an individualized level that would hold grant recipients individually accountable for effective results? So far, preliminary examination indicates the answers are no. And when you don't define where you're going, every road you take still leaves you lost. So we're hoping we can get some direction today.

The numbers indicate we are failing as a Nation, and we darn well better come to terms with that. The 43,000 lives lost last year, the thousands of babies born addicted to opiates tell us the terrible toll this epidemic has taken. You've heard my thoughts about the Government-sponsored promotion of what I've characterized as addiction maintenance, and I refer to buprenorphine as heroin helper, not because the medication is altogether lacking, because it is helpful, but rather, because infrastructure the Federal Government has created for the use of this highly potent and important medication is not fully working and, worse yet, in many cases, contributing to the growing problem. This has to be fixed, and I hope we'll find some solutions, and that is what we need to discuss today openly, honestly, and humbly.

If we do not reverse the current trend, where is this going to end? How many millions of citizens do we want to have on opiate maintenance? How many more must die? And how many more lives and dreams must be shattered before we recognize the depth of this national scourge?

Now, I don't believe in better living through dependency. And, again, please do not misconstrue this critique as a general indictment of opiate maintenance. It is not. For some people, opiate maintenance is the most appropriate bridge treatment, and there should be no shame or stigma associated with it. But opiate maintenance therapy should not be the only treatment offered to the opiate-dependent individuals, and it is not the only goal.

What patients on opiate maintenance can be successfully transition off of these medications? What protocols are best for affecting this transition? What are the best practice for prevention of relapse for those patients who end opiate maintenance treatment? There are nonaddictive medications approved for this use, but are these medications widely available and how well do they work?

The diversion of buprenorphine for illicit nonmedical use is a related problem, because this is how the opiate epidemic can be spread. According to the DEA, buprenorphine is the third most often seized prescription opiate by law enforcement today. Where is a call to modernize our existing opiate addiction treatment system to ensure that the right patient gets the right treatment at the right time? Why aren't we hearing about expanding access to non-addictive narcotic treatments that have zero potential for abuse or diversion, such as Naltrexone and evidence-based counseling? These are all incredibly important tools, and we want to make sure HHS talks more about these.

Last week, Dr. Westley Clark, the former Director of SAMHSA Center for Substance Abuse treatment and the man who oversaw the growth of buprenorphine over the past decade declared before the American Society of Addiction Medicine that many buprenorphine practices have become pill mills where doctors and dealers were increasingly indistinguishable and physician negligence and alleged laboratory fraud prevailed. The problem is not with buprenorphine, however. The problem lies with current practices, and this is what we need to discuss.

I consider opiate maintenance as a bridge for those with addiction disorders to cross over in the recovery process. And as I said, it is not a final destination. We seek to lay out a vision for recovery that includes complete withdrawal from opiates as an option. For cancer, for diabetes, for AIDS, we want people to be free of the diseases, not just learn to live with it. We need to commit the same sorts of things through our research and clinical efforts that boldly declare what we must change here.

I thank our witnesses for being here today.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Today we convene the third in a series of hearings examining the growing problem of prescription drugs and heroin addiction that is ravaging our country. This is our Nation's single biggest public health concern.

Over the past five weeks, this subcommittee has heard from addiction experts working within local communities and our leading academic and research centers.

Dr. Robert DuPont, the former White House Chief on drug control policy and the first director of the National Institute on Drug Abuse, testified that Federal programs lack directions and standards on treating addiction as a chronic condition and noted: What is being done to follow-up with patients to prevent relapses and put them on a path of real recovery? He challenged us to even ask the most fundamental question: what is recovery? Dr. Anna Lembke of Stanford Medical School provided critical testimony on how we must revise our healthcare quality measures to reduce over-prescribing, reform medical privacy regulations, and incentivize use of Prescription Drug Monitoring Programs. We know that those with opioid-addiction disorders need a broad range of treatment options, and that many with substance abuse disorders have a co-occurring psychiatric disorder—but we need to tear down Federal policy and funding barriers that keep us from treating both simultaneously.

About three weeks ago, one of today's witnesses—Mr. Michael Botticelli, the Director of the Office of National Drug Control Policy—presented the following slide at the National Rx Summit on major causes of death from injury 1999–2013. While the trends of other major causes of death such as auto accidents went down, drug poisoning continued to go up 21 percent from 2008 to 2013. In many States these numbers are soaring at high double digit rates of increase. As Mr. Botticelli has indicated to me privately and at the Rx Summit, we must do better and we have much work to do.

Today, hear from the Federal agencies charged with providing guidance, direction, and leadership in our Nation's public health response to the opioid epidemic.

No Federal agency has a more central role in this ongoing epidemic than the Department of Health and Human Services (HHS). HHS and its Substance Abuse and Mental Health Services Administration (SAMHSA) are responsible for leading our Nation's public health response to the opioid, heroin abuse and addiction crisis. SAMHSA regulates our country's 1,300 opioid treatment programs, and SAMHSA is responsible for certifying the 26,000 physicians who prescribe the most commonly used opioid maintenance medication: buprenorphine. According to testimony provided by SAMHSA before this subcommittee in April of last year, there were nearly 1.5 million people treated with these opioid maintenance medications in 2012—which is a 5-fold increase in the last 10 years. Has SAMHSA defined the goal of recovery for what these federally subsidized treatment programs are supposed to accomplish? Is SAMHSA collecting and evaluating meaningful data at an individualized level that would hold grant recipients individually accountable for effective results? So far, our preliminary examination indicates the answers are no. And when you don't define where you are going, every road you take still leaves you lost.

The numbers indicate we are failing as a nation, and we darn well better come to terms with that. The 43,000 lives lost last year, the thousands of babies born addicted to opioids tell us the terrible toll this epidemic has taken. You have heard my thoughts about the Government-sponsored promotion of what I have characterized as "addiction maintenance."

I have referred to buprenorphine as a "heroin helper" not because the medication is altogether lacking, but rather, because the infrastructure the Federal Government has created for the use of this highly potent and important medication is not working and worse yet, contributing to the growing problem. It has to be fixed, and that is what we need to discuss—honestly, openly, humbly.

If we do not reverse the current trend, where will it end? How many millions of citizens do we want to have on opioid maintenance? How many more must die? How many more lives and dreams must be shattered before we recognize the depth of this scourge?

I do not agree in "better living through dependency."

Again, please do not misconstrue this critique as a general indictment of opioid maintenance. It is not. For some people, opioid maintenance is the most appropriate bridge treatment and there should be no shame or stigma associated with it. But opioid maintenance therapy should not be the only treatment offered to opioid dependent individuals, nor the only goal.

What patients on opioid maintenance can be successfully transitioned off of these medications? What protocols are best for effecting this transition?

What are the best practices for the prevention of relapse for those patients who end opioid maintenance treatment? There are non-addictive medications approved for this use, but are these medications widely available?

The diversion of buprenorphine for illicit, non-medical use is a related problem because this is how the opioid epidemic can be spread. According to the DEA,

buprenorphine is the third most often seized prescription opioid by law enforcement today.

Where is the call to modernize our existing opioid addiction treatment system to ensure that the right patient gets the right treatment at the right time? Why aren't we hearing about expanding access to nonaddictive, non-narcotic treatments that have zero potential for abuse or diversion, such as naltrexone and evidence-based counseling? These are incredibly important tools that are barely mentioned in the HHS plan.

Last week, Dr. Westley Clark, the former Director of SAMHSA's Center for Substance Abuse Treatment, and the man who oversaw the growth of buprenorphine over the past decade, declared before the American Society of Addiction Medicine that many buprenorphine practices had become pill mills where "Doctors and Dealers" were increasingly indistinguishable and "Physician Negligence" and "Alleged Laboratory Fraud" prevailed. The problem is not with buprenorphine, however. The problem lies with current practice and this is what we need to discuss.

I consider opioid maintenance as a bridge for those with addiction disorders to cross over in the recovery process. It is not a final destination. I seek to lay out a vision for recovery that includes complete withdrawal from opioids as an option. For cancer, diabetes, AIDS, we want people to be free of the disease, not learn to just live with it. We need to commit to research and clinical efforts that boldly declare that we must change.

Mr. MURPHY. And I now recognize the ranking member of the subcommittee, Ms. DeGette from Colorado, for 5 minutes.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman.

I think it's really important to hear from our witnesses today about the work the Federal Government is doing to address this serious public health issue, and I know all of the agencies represented before us do critical work to prevent and treat this epidemic.

In March, Secretary Burwell announced an initiative to combat the opioid crisis. I applaud the Department's actions, and I'm gratified to hear that this is one of the Secretary's top priorities. I want to hear more about this initiative today and how all the agencies before us are working together to accomplish its goals. But at the same time, I have some hard questions about our approach to caring for those who have substance abuse disorders.

Last week, we heard from a panel of medical experts who have vast experience in treating opioid addiction. Unfortunately, as the chairman said, they gave us a fairly bleak view of the opioid treatment landscape in this country. For example, one witness, Dr. Adam Bisaga, a psychiatrist at Columbia University and a research scientist at the New York State Psychiatric Institute, told the committee that the majority of patients being treated for opioid addiction received treatment that is both, "outdated" and "mostly ineffective." He described this approach of rapid detoxification, followed by an abstinence-only method without the use of important treatment medications. Dr. Bisaga added that this is potentially dangerous because it raises the risk of an overdose if a patient relapses.

As troubling as this testimony from our last hearing was, today we have Dr. Volkow on our panel, who is one of the world's top experts on addiction research. And she notes—I'm sure you'll talk more about this, Doctor—in her written testimony that, "Existing

evidence-based prevention and treatment strategies are highly underutilized across the United States.”

Why is that, Mr. Chairman? Why do we have experts week after week telling us that the bulk of the treatment Americans are receiving for this devastating disease are ineffective, outdated, and not evidence based.

We need to be asking ourselves some tough questions. For example, Dr. Westreich, the president of the American Academy of Addiction Psychiatry, told us last week, “Patients and their families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse.” Are patients enrolling in treatment getting sufficient data so they can make medically informed choices? Are families and loved ones being told what approaches have high failure rates before choosing an approach to treatment? Frankly, this is not a decision that should be taken lightly. Getting ineffective treatment may not only be financially costly, but it may result in a fatal relapse.

Finally, Mr. Chairman, recent testimony, including some I saw in the written statements for today, raises important questions about whether taxpayer dollars should fund certain approaches for combating this opioid epidemic over others. This is an issue I’ve been talking about week after week. We all agree that we need the most effective treatment, and our experts agree that this treatment needs to be a broad menu of options that is different from patient to patient.

So we might not have a silver bullet to cure opioid addiction at this point, but we do know what treatments work better than others. Evidence tells us—and all the medical experts we heard from last week agree—that for most patients a combination of medication-assisted treatment and behavioral treatment, such as counseling and other supportive services, is the most effective way to treat opioid addiction. If that’s the case, we should pursue more policies that encourage this approach as a clear option and steer away from any efforts that are not evidence based. It’s costly, and it’s dangerous to the patient.

So I hope we can all work together to fight this epidemic, and I do look forward to hearing from all of our witnesses. I’m glad Secretary Burwell and the department are devoting serious attention to addressing both the prevention and treatment sides of this problem.

And, Mr. Chairman, this has been a really great series. I’m happy to have a whole investigation like this in this committee. There’s one group that we haven’t heard from yet, I’m hoping—

Mr. MURPHY. States.

Ms. DEGETTE. Good. The States. We haven’t heard from the States yet. It’s critical we hear from them because that’s where the rubber is hitting the road. We need to hear what the States are doing to address this problem and understand the reasoning behind some of the choices being made. Some States are picking effective treatment methods, and others are not.

So I think we need a multifaceted approach that this is what our research has showed, and I know we can work together to continue this important investigation.

I just want to add one more note. The witnesses and the audience may see members jumping in and running out. We have another hearing in Energy and Commerce Committee going on down on the first floor, so people will be coming and going. But I know certainly, from my side of the aisle, people recognize this is a very serious issue. Thank you.

Mr. MURPHY. Thank you. And I know that they'll be calling votes at 9:30 for first vote series.

Ms. DEGETTE. I thought it was at 11:00.

Mr. MURPHY. Something has changed. First and only vote series of the day. I'm here for the duration, so we want to hear from you and hopefully the members.

And now we recognize Mr. Upton.

Mr. UPTON. We really are going to have votes at 9:30?

Mr. MURPHY. That's what it says now.

Mr. UPTON. Well, I'm going to submit my statement for the record then.

Mr. MURPHY. OK. All right.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today we continue our important review of the opioid abuse epidemic. In recent weeks we have heard valuable testimony from academics and State and local leaders, including folks on the frontlines in Southwest Michigan, and today we will hear what the Federal Government is doing to combat this pressing issue.

The abuse of painkilling opioids and heroin is a complex and growing public health crisis that has sadly been outpacing the Nation's efforts to reverse this epidemic. A lot of people are dying, and a lot of families are suffering. In Kalamazoo County, where the reality of heroin overdoses has hit hard, we remember two young women who were friends. In 2008, we lost Amy Bousfield at 18 years old. In 2012, her friend Marissa King died at 21 years old. Marissa began using heroin in 2009, despite having lost two friends to the drug. Marissa was diagnosed with bipolar disorder, had struggled with depression, and had abused prescription drugs before turning to heroin after graduating from high school.

Every community has been hit by heartbreak. According to the Michigan Department of Community Health, "Unintentional poisoning deaths in Michigan involving opioids comprise 20 percent of unintentional poisoning deals in 2012, compared to 11 percent in 1999. Unintentional poisoning deaths involving opioids increased more rapidly than those from any other drug." This subcommittee's diligent review of every perspective of this issue is important.

Last week, we took an important step. The House approved bipartisan legislation coauthored by the full committee Vice Chairman Marsha Blackburn, and Representatives Tom Marino, Peter Welch, and Judy Chu to clarify language in the Controlled Substances Act and promote collaboration between agencies and stakeholders to ensure patients have access to medications.

But this subcommittee's hearings have shined a light on how much more needs to be done. Our review has introduced us to many health professionals, scientists, community leaders, and public servants who are working their hearts out to make a difference and to help reduce this problem. There are a number of worthy ideas on how to strengthen the Federal response.

To take on the enormous challenge posed by the opioid abuse epidemic, we need to be unified and find common ground. These hearings provide a foundation for this committee to proceed in a bipartisan fashion to take constructive and effective actions. I am ready to work with my colleagues on the committee on both sides of the aisle, the president, Secretary Burwell, and the rest of the administration to produce positive results in fighting this epidemic for the American people.

We want to help. I welcome our distinguished Federal Government witnesses and look forward to their testimony.

Mr. UPTON. Yield back.

Mr. MURPHY. All right.

Mr. Pallone, 5 minutes.

Mr. PALLONE. I'll do the same, Mr. Chairman, because we both have to go to the other hearing.

Mr. MURPHY. OK.

Mr. UPTON. It's his bill. It's his bill we're talking about.

Mr. MURPHY. See how much we get along?

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Mr. Chairman, thank you for holding this hearing today—the third in a series on the opioid abuse epidemic. This problem has affected every one of our districts, and I am glad this subcommittee is taking a serious look at this issue.

Today's hearing gives us the opportunity to hear from Federal Government agencies about what they are doing to tackle the opioid addiction crisis. I am pleased to see that Secretary Burwell and the Department are taking important steps on both the prevention and the treatment of opioid abuse and I look forward to working with them on addressing this burgeoning crisis. To that end, it is critical also that we approach this problem on both sides of this issue—upstream, where overprescribing is occurring, and downstream, where better treatment across this country is desperately needed.

The opioid addiction and abuse epidemic is inextricably tied to the overprescribing of these drugs for the treatment and management of chronic pain. I want to hear from you about how we can reduce the overprescribing of opioids and assist medical professionals in making informed prescribing decisions.

On the treatment side, we need to focus our attention on what works. There is consensus in the medical community that medication-assisted treatment—or MAT—is an essential component of effective treatment. However, it is still not available in large parts of the country and as others have already told this committee, many Americans are receiving outdated and ineffective treatment. We need to understand why that is the case and how we can increase access to the most effective treatment protocols currently available.

I also want to use today's hearing as an opportunity to hear from these Federal agencies about the implementation of the Affordable Care Act. When we passed the law, we took significant steps to expand access to health care for all Americans, including those with substance use disorders.

For many, the lack of insurance or the cost of treatment presents an insurmountable barrier to receiving the treatment help they need. The Affordable Care Act addresses some of these problems by expanding insurance coverage and requiring that insurance cover the cost of substance abuse services. This will mean that millions of people will have access to the tools they need to break their addictions.

Additionally, the Affordable Care Act provides us with a historic opportunity to transform a fragmented, underfunded system for treating substance abuse disorders into one that promotes coordinated, patient-centered care. I look forward to hearing from Dr. Frank and others about how the Affordable Care Act is transforming the landscape for behavioral health services, and what more needs to be done to truly integrate behavioral health services into our broader healthcare system.

Thank you again for holding this important hearing and to all our witnesses. I look forward to continuing our work on this issue.

I yield my remaining time to Rep. Kennedy.

Mr. MURPHY. Is there anybody else on either side that needs recognition? Go right into this.

OK. Let me find my—

Ms. DEGETTE. No. Wait, wait. Mr. Kennedy.

Mr. PALLONE. Oh, he wanted a minute. Mr. Chairman, can I yield just 1 minute to Mr. Kennedy?

Mr. MURPHY. Yes. You can yield your minutes to Mr. Kennedy of Massachusetts.

Mr. KENNEDY. Thank you very much for the consideration. I yield back.

Mr. MURPHY. OK. All right. Let me now introduce the witnesses on the panel for today's hearing. We have the Honorable Michael

Botticelli, the Director of the Office of National Drug Control Policy, which is part of the Executive Office of the President. Welcome here. Dr. Richard Frank, the Assistant Secretary For Planning and Evaluation at the U.S. Department of Health and Human Services; Dr. Nora Volkow, who is the Director of the National Institute on Drug Abuse with the National Institutes of Health; Dr. Douglas Throckmorton, who is the Deputy Director of the Center for Drug Evaluation and Research of the Food and Drug Administration; Dr. Debra Houry, the Director of the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention; the Honorable Pamela Hyde, the Administrator for the Substance Abuse and Mental Health Services Administration; and Dr. Patrick Conway, the Deputy Administrator for Innovation and Quality and the CMS Chief Medical Officer at the Centers for Medicare and Medicaid Services. Welcome.

You are aware that—now swearing in the witnesses—the committee is holding an investigative hearing and, when doing so, has a practice of taking testimony under oath. Do you have any objection to testifying under oath?

None of the witnesses have objection. So the Chair then advise you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel today? And none of the witnesses say so.

So, in that case, please rise. Raise your right hand. I'll swear you in.

Do you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth?

Thank you. All the witnesses answered in the affirmative, so you are now under oath and subject to the penalties set forth in title 18, section 1001 of the United States Code.

You may now each give a 5-minute opening statement. Please stick to the 5 minutes. If you don't have to fill it, that's OK, too. We'd like to get through.

Mr. Botticelli.

STATEMENTS OF MICHAEL P. BOTTICELLI, DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; RICHARD G. FRANK, PH.D., ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH; DOUGLAS C. THROCKMORTON, M.D., DEPUTY DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; DEBRA HOURY, M.D., M.P.H., DIRECTOR, NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL, CENTERS FOR DISEASE CONTROL AND PREVENTION; PAMELA S. HYDE, J.D., ADMINISTRATOR, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION; AND PATRICK CONWAY, M.D., M.Sc., DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY, AND CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES

STATEMENT OF MICHAEL P. BOTTICELLI

Mr. BOTTICELLI. Thank you, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee for the opportunity to provide testimony to you today about the administration's efforts to address the opioid epidemic in the United States.

Mr. Chairman, as you recognized, in 2013 almost 44,000 Americans died of a drug overdose. That's one drug overdose death every 12 minutes. Using ONDCP's role as the coordinator of the Federal Drug Control agencies, in 2011, we published the administration's Prescription Drug Abuse Prevention Plan to address the sharp rise in prescription opioid drug abuse in this country since 1999. As you know, the plan consists of action items categorized under four pillars: Education of patients and prescribers; increased prescription drug monitoring; proper medication disposal; and informed law enforcement.

With the work of our HHS partners here today, and other Federal partners as part of the Interagency Prescription Drug Work Group convened by ONDCP, we have made some strides in each of these areas, but there is much more to be done.

Since time in graduate medical education programs devoted to the identification of treatment of substance abuse disorders is rare, we have worked with our Federal partners to develop continuing education programs about substance abuse, managing pain appropriately, and treating patients using opioids more safely. Many prescribers in Federal agencies, including HHS, are receiving this important training. Despite this, a large percentage of prescribers have not availed themselves of this training. Therefore, the administration continues to press for mandatory prescriber education tied to controlled substance licensure. I am pleased that Secretary Burwell has expressed her support for working with Congress to set requirements for specific training for opioid prescribers.

Today, all States but one, Missouri, have prescription drug monitoring programs that allow prescribers to check on drug interactions as well as alert them to the signs of dependence on opioids. Missouri is also working to authorize a PDMP program. With almost all States implementing PDMPs, we are focusing on improv-

ing State-to-State data sharing, and improving access to PDMP data within the health record systems providers use every day.

In October, the Drug Enforcement Administration's final regulation on controlled substances disposal became effective. ONDCP and our Federal partners and stakeholders have begun to inform the public about these regulations and look to ways to stimulate more local disposal programs in partnerships with pharmacies, local government, community groups, and local law enforcement.

And the work of our law enforcement partners at the Federal, State, and local levels is ongoing. Those engaged in fraud across the drug control supply chain are being investigated and prosecuted.

Recent data shows we are seeing an overdose from prescription opioids leveling off in this country, but a dramatic 39 percent increase in heroin overdoses from 2012 to 2013. This is creating an additional need for treatment in a system where a well-known gap between treatment capacity and demand already exists. Therefore, we must redouble our efforts to address people who are misusing prescription opioids, since we know this is a major risk factor for subsequent heroin use.

Earlier this week, the administration held the inaugural meeting of the congressionally mandated interagency Heroin Task Force. Mary Lou Leary, our Deputy Director for State, Local, and Tribal Affairs, is one the cochairs for this committee. In addition, the President's FY '16 budget request includes \$99 million in additional funding for treatment and overdose prevention efforts.

We have also been working to increase access to the emergency opioid overdose reversal drug, naloxone, and to promote Good Samaritan laws so that witnesses can take steps to help save lives. Many police and fire departments have already trained and equipped their personnel with this life-saving drug, and loved ones of people with opioid drug use disorders are equipping themselves as well.

And while law enforcement and other first responders have an important role to play, the medical establishment also must become more engaged to identify and treat heroin and prescription opioid use disorders. Every day, these people appear in our emergency departments and other medical settings, and more models and interventions are needed to get these individuals engaged in care.

We also need to expand availability of evidence-based opioid use disorder treatments. Medication-assisted treatment, which uses FDA-approved medications, combined with behavioral and other recovery supports, has been shown to be the most effective treatment for opioid use disorders. Decisions about the most appropriate treatment options and their duration need to be agreed upon by both the patient and the treatment provider.

We must also provide community supports, such as access to housing, employment, and education, to give patients the functional tools they need to lead healthier lives and fully integrate into the community as part of their recovery process.

While we support multiple pathways to recovery, the literature shows that short-term treatment, such as detoxification alone, is not effective and carries risk of relapse and overdose death. Because of the lack of availability of evidence-based maintenance

treatments and the strong connection between injection of opioid drugs and infectious disease transmission, we also promote the use of public health strategies that will help prevent the further spread of infectious disease. The HIV and hepatitis C outbreak in Scott County, Indiana, is a stark reminder of how opioid use can spread other diseases, how comprehensive public health strategies, such as syringe exchange programs, need to be part of the response to the opioid use epidemic, and how rural communities that have limited treatment capacity may experience additional public health crises.

Finally, we are continuing our efforts to address neonatal abstinence syndrome. Research published just yesterday shows that the incidence of NAS has grown nearly fivefold between 2000 and 2012 and that 81 percent of the 2012 hospital charges for NAS were attributed to Medicaid. We must consider that the best interest of babies with NAS is often served by best addressing the interests of the mother. Therefore, we need to provide safe harbor for pregnant and parenting women seeking prenatal care and treatment.

In conclusion, we look forward to working with Congress and our Federal partners on the next stage of action to address this epidemic. Thank you.

[The prepared statement of Mr. Botticelli follows:]



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

**“What is the Federal Government Doing to
Combat the Opioid Abuse Epidemic?”**

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

Friday, May 1, 2015
9:00 a.m.
2322 Rayburn House Office Building

Written Statement
of
Michael P. Botticelli
Director
Office of National Drug Control Policy

Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for this opportunity to address the public health and safety issues surrounding the diversion and non-medical use of opioid drugs – including prescription painkillers and heroin – in the United States.

As you know, the Office of National Drug Control Policy (ONDCP) was established in 1988 by Congress with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, our office establishes policies, priorities, and objectives for the Nation's drug control programs and ensures that adequate resources are provided to implement them. We also develop, evaluate, coordinate, and oversee the international and domestic anti-drug efforts of Executive Branch agencies and ensure such efforts sustain and complement state and local drug policy activities.

At ONDCP, we are charged with producing the *National Drug Control Strategy (Strategy)*, the Administration's primary blueprint for drug policy, along with a national drug control budget. The *Strategy* is a 21st century plan that outlines a series of evidence-based reforms that treat our Nation's drug problem as a public health challenge, not just a criminal justice issue. It moves beyond an outdated "war on drugs" approach, and is guided by what science, experience, and compassion demonstrate about the true nature of drug use in America.

The considerable public health and safety consequences of nonmedical prescription opioid and heroin use underscore the need for action. Since the Administration's inaugural *2010 National Drug Control Strategy*, we have deployed a comprehensive and evidence-based strategy to address overdose deaths and opioid use disorders. The Administration has significantly bolstered support for substance use disorder treatment and overdose prevention; coordinated a government-wide response to the epidemic consequences from nonmedical prescription drug use; and pursued action against criminal organizations trafficking in opioid drugs.

Trends and Consequences of Opioid Use

The nonmedical use of opioids – a category of drugs which include heroin and prescription pain relievers like oxycodone and hydrocodone – is having a considerable impact on public health and safety in communities across the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 120 Americans on average died from a drug overdose every day in 2013. Of the nearly 44,000 drug overdose deaths in 2013, opioid pain relievers were involved in over 16,200, while heroin was involved in over 8,200. Overall, drug overdose deaths now outnumber deaths from gunshot wounds (over 33,600) or motor vehicle accidents (over 35,400) in the United States.¹

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2013 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on January 30, 2015.

As this Subcommittee knows, the diversion and nonmedical use of prescription opioid medications has been of serious concern at the national, state, and local levels. Increases in admissions to treatment for substance use disorders,² drug-related emergency department visits,³ and, most disturbingly, overdose deaths⁴ attributable to nonmedical prescription drug use place enormous burdens upon communities across the country.

In 2013, over 4.5 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.⁵ This makes nonmedical prescription pain reliever use more common than use of any category of illicit drug in the United States except for marijuana. By comparison, approximately 289,000 Americans reported past month use of heroin.⁶ Heroin use remains relatively low in the United States when compared to other drugs; however, there has been a troubling increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 681,000 in 2013.⁷ This trend comports with other indicators, including recent reporting from the National Institute on Drug Abuse's (NIDA) Community Epidemiology Work Group, which found that several U.S. cities, including Atlanta, Baltimore, Boston, Chicago, Cincinnati, Denver, Miami, Minneapolis, San Diego, Seattle, and St. Louis, indicated increases in heroin use. In addition, heroin remained at relatively stable but high levels in Detroit, New York City, and Philadelphia.⁸ The Drug Enforcement Administration (DEA) also reports an over 300 percent increase of heroin seizures at the Southwest border from 2008 to 2013.⁹

The nonmedical use of these opioids translates into serious health consequences. In 2013 alone, approximately 1.9 million Americans met the diagnostic criteria for abuse or dependence on prescription pain relievers, while heroin accounted for approximately 517,000 people with

² Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) 2001-2011, National Admissions to Substance Abuse Treatment Services*. U.S. Department of Health and Human Services. [2013]. Extracted April 2013.

³ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2013 on CDC WONDER Online Database, released 2015.

⁵ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2013.htm#tab7.3b>

⁶ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2013.htm#tab7.3A>

⁷ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2013.htm#tab7.2A>

⁸ National Institute on Drug Abuse. Highlights and Summaries from January 2014 Reports. Available: <http://www.drugabuse.gov/about-nida/organization/interest-groups-consortia/community-epidemiology-work-group-cewg/highlights-summaries-january-2014-reports>

⁹ National Seizure System, El Paso Intelligence Center, extracted January 25, 2014.

past year use or dependence. Both of these figures represent significant increases from just a decade earlier.¹⁰

Beyond the many lives taken by overdoses involving these medications, prescription opioids are also associated with significant consequences for our health care system. In 2011 alone, 1.2 million emergency department (ED) visits involved the non-medical use of all prescription drugs.¹¹ Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class, accounting for approximately 488,000 visits. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just 7 years earlier in 2004 (173,000). Among specific opioid drugs in 2011, oxycodone accounted for the largest share (31 percent) of ED visits; there were 100,000 more visits involving oxycodone in 2011 than in 2004; this is an increase of 263 percent in the number of such visits from 2004 to 2011. While ED admissions involving heroin have remained relatively flat over the past several years, the drug was still involved in nearly 260,000 visits in 2011.

Similar trends are reflected in the country's substance use disorder treatment system. Data show a nearly four-fold increase in the past ten years of treatment admissions for individuals primarily abusing prescription pain relievers, from 43,000 in 2002 to 164,000 in 2012. Heroin treatment admissions remained flat over the same time period, but still accounted for 285,000 admissions in 2012.¹²

There has been considerable discussion around potential connections between the non-medical use of prescription opioids and heroin use. There is evidence to suggest that some users, specifically those with chronic opioid addictions, will substitute heroin for prescription opioids, since heroin is often cheaper than prescription drugs. A recent report from the Substance Abuse and Mental Health Services Administration (SAMHSA) found that four out of five recent heroin initiates had previously used prescription pain relievers non-medically. However, only a very small proportion (3.6%) of those who recently had started using prescription drugs non-medically initiated heroin use in the following five-year period.¹³ Therefore, focusing our efforts to prevent first-time nonmedical opioid pain reliever use can help reduce heroin initiation.

We also know that substance use disorders, including those driven by opioids, are a progressive disease. We know from survey data that as an individual's non-medical use of

¹⁰ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7pcTabs1to45-2013.htm#tab7.40A>

¹¹ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

¹² Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment Admissions by Primary Substance of Abuse, United States [2002 through 2012 – Table 1.1a]*. U.S. Department of Health and Human Services. [July 2014]. Available: http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_Treatment_Episode_Data_Set_National_Tables.htm

¹³ Substance Abuse and Mental Health Services Administration. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Department of Health and Human Services. [August 2013]. Available: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

prescription opioids becomes more frequent or chronic, that person is more inclined to purchase the drugs from dealers/prescriptions from multiple doctors, rather than simply getting them for free from a friend or relative.¹⁴ Qualitative data indicates as tolerance, dependence or craving increases, users tend to obtain more opioid sources and at times will select lower cost alternatives such as heroin as a way to meet and afford escalating opioid needs.^{15,16,17}

The Administration's Response

Since 2009, the Obama Administration has deployed a comprehensive and evidence-based strategy to address opioid drug misuse and its consequences. The Administration has coordinated a Government-wide response to this epidemic, significantly bolstered support for medication-assisted opioid treatment and overdose prevention, and pursued action against criminal organizations trafficking in opioid drugs. President Obama's inaugural *National Drug Control Strategy*, released in May 2010, labeled opioid overdose a "growing national crisis" and laid out specific actions and goals for reducing nonmedical prescription opioid and heroin use.¹⁸

Nonmedical use of prescription drugs represents the bulk of illicit opioid use in America, and our response to this public health emergency focuses not only on preventing the diversion and abuse of prescription drugs, but also decreasing the number of Americans dying from opioid overdose every day. In April 2011, the Administration released a comprehensive *Prescription Drug Abuse Prevention Plan (Plan)*,¹⁹ which created a national framework for reducing prescription drug diversion and misuse. This *Plan* built upon the goal identified in the *National Drug Control Strategy* to reduce drug-induced deaths by 15 percent by 2015 and augmented that goal with a distinct goal to reduce unintentional overdose deaths related to opioids by 15 percent within 5 years. The *Plan* focuses on improving education for patients and healthcare providers, supporting the expansion of state-based prescription drug monitoring programs, developing more convenient and environmentally responsible disposal methods to remove unused and unneeded medications from the home, and reducing the prevalence of pill mills and doctor shopping through targeted enforcement efforts.

The Administration has made considerable progress in all four areas of the *Plan*. To start, much progress has been made in expanding available continuing education for prescribers.

¹⁴ Unpublished estimates from Substance Abuse and Mental Health Services Administration. *National Survey on Drug Use and Health*. 2009-2012, March 2014.

¹⁵ Lankenau SE, Teti M, Silva K, Jackson Bloom J, Harocopoulos A, Treese M. Initiation into prescription opioid misuse amongst young injection drug users. *Int J Drug Policy*. 2012 Jan;23(1):37-44. doi: 10.1016/j.drugpo.2011.05.014. Epub 2011 Jun 20. PMID: 21689917 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3196821/>

¹⁶ Lankenau SE, Teti M, Silva K, Bloom JJ, Harocopoulos A, Treese M.J. Patterns of prescription drug misuse among young injection drug users. *Urban Health*. 2012 Dec;89(6):1004-16. doi: 10.1007/s11524-012-9691-9. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3531346/>

¹⁷ Sarah G. Mars, Philippe Bourgois, George Karandinos, Fernando Montero, Daniel Ciccarone. "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting *Int J Drug Policy*. Author manuscript; available in PMC 2015 March 1. Published in final edited form as: *Int J Drug Policy*. 2014 March; 25(2): 257–266. Published online 2013 October 19. doi: 10.1016/j.drugpo.2013.10.004 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3961517/pdf/nihms533727.pdf>

¹⁸ Office of National Drug Control Policy. *2010 National Drug Control Strategy*. Executive Office of the President. [2010]. Available: <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndes2010.pdf#page=49>

¹⁹ Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf

Managing patients' pain is a crucial area of clinical practice, but research indicates that health care practitioners receive little training on pain management, safe opioid prescribing, or recognizing and treating substance use disorders.^{20,21} Several states, including Iowa,²² Kentucky,²³ Massachusetts,²⁴ Ohio,²⁵ Tennessee,²⁶ New Mexico,²⁷ and Utah,²⁸ have passed legislation mandating education for prescribers, and we strongly encourage other states to explore this as an option.

The Administration developed and has made available free and low-cost training options available for prescribers and dispensers of opioid medications via several sources. SAMHSA provides such training. In addition, ONDCP worked with NIDA to develop "NIDAMED," two free, online training tools on safe prescribing for pain and on managing pain patients who use prescription opioids non-medically. Since its launch in late 2012 through February 2015, 58,166 clinicians completed the first NIDAMED course, and 48,189 clinicians completed the second course for continuing medical education credit. In total, 115,116 clinicians viewed part or all of the first course, and 89,654 viewed part or all of the second course. Pharmacists can also access these courses, and as of March 2014, members of the American Association of Nurse Practitioners and the American Academy of Physician Assistants were able to take these courses for credit.

The Food and Drug Administration (FDA) now requires manufacturers of extended-release and long-acting (ER/LA) opioid pain relievers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy (REMS) for these drugs. This program is arguably the most ambitious as FDA expects to train at least 60 percent of the approximately 320,000 prescribers of these medications within the first four years of the program.²⁹

²⁰ Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

²¹ U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: <http://www.gao.gov/assets/590/587301.pdf>

²² Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available: http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

²³ Kentucky Board of Medical Licensure. "House Bill 1." Commonwealth of Kentucky. [2012]. Available: <http://kbml.ky.gov/hb1/Pages/default.aspx>

²⁴ Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available: <http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html>

²⁵ General Assembly of the State of Ohio. "129th General Assembly – Amended Substitute Senate Bill Number 83." [2012]. Available: http://www.legislature.state.oh.us/bills.cfm?ID=129_SB_83

²⁶ State of Tennessee. "Public Chapter No. 430 – Senate Bill 676." [April 18, 2013]. Available: <http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>

²⁷ New Mexico Medical Board. "Title 16 Chapter 10 Part 14 Section 11 – "Pain Management Continuing Education." [effective November 2012]. Available at: http://www.nmmr.state.nm.us/pdf/Files/Rules/NMAC16.10.14_PainManagement.pdf

²⁸ Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act*. 58-37-6.5. State of Utah. [May 2012]. Available: <http://www.dopl.utah.gov/laws/58-37.pdf#page=24>

²⁹ Food and Drug Administration. "Questions and Answers: FDA approves a Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics." Department of Health and Human Services. [updated March 2013]. Available: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm#Q8>

The Department of Health and Human Services (HHS) has implemented education requirements for its agency health care personnel, including professionals serving tribal communities through the Indian Health Service (IHS), those working with underserved populations through the Health Resources and Services Administration (HRSA), and personnel attending to biomedical research trial participants at the Clinical Center of the National Institutes of Health (NIH). Similar efforts have been implemented by the Bureau of Prisons, Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Although FDA has made excellent progress with the REMS, it alone cannot address the dearth of critical and necessary opioid prescriber training. For one thing, REMS only covers ER/LA opioids. Also, while there are around one million physicians eligible to prescribe controlled substances, FDA estimates that fewer than 100,000 prescribers will have completed REMS continuing education by July 2015. While educating this number of prescribers is valuable, it is unrealistic to think that prescribing culture will change substantially without training a majority of subscribers. From 2010 to 2013, prescription opioid overdose deaths have decreased – but only by 2 percent. We must do more to ensure all prescribers have the knowledge and tools they need to prevent non-medical prescription drug use. That is why we, like FDA, continue to recommend a mandatory continuing education requirement tied to controlled substance licensure.

In March, HHS announced a comprehensive, evidence-based initiative aimed at reducing opioid dependence and overdose. Among the three priority areas of the initiative are efforts to train and educate health professionals on safe opioid prescribing, including the development of prescribing guidelines for chronic pain by the CDC.

The FDA has also taken a number of steps to help safeguard access to opioid pain relievers while reducing risks of non-medical use and overdose. In September 2013, ONDCP joined the FDA to announce significant new measures to enhance the safe and appropriate use of ER/LA opioid analgesics.³⁰ FDA required class-wide labeling changes for these medications, including modifications to the products' indication for severe pain, warnings around use during pregnancy, as well as post-market research requirements. FDA also announced that manufacturers of ER/LA opioids must conduct further studies and clinical trials to better assess risks of misuse, addiction, overdose, and death. In April 2013, FDA approved updated labeling for reformulated OxyContin that describes the medication's abuse-deterring properties. These properties make the drug more difficult to inject or use nasally.³¹ And in December 2013, FDA announced its recommendation that DEA reschedule hydrocodone combination products from Schedule III to Schedule II of the Controlled Substances Act, which requires more stringent standards for storage, record keeping, and prescribing. In August 2014, DEA issued a Final Rule:

³⁰ Food and Drug Administration. "ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements – Letter to ER/LA opioid application holders." Department of Health and Human Services. [September 2013]. Available: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>

³¹ "Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness." Federal Register 78:75 (April 18, 2013) p. 23273. Available: <http://www.gpo.gov/fdsys/pkg/FR-2013-04-18/pdf/2013-09092.pdf>

Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, which became effective in October 2014.³²

The Administration is also educating the general public around opioid use. ONDCP's Drug-Free Communities (DFC) Support Program currently funds 680 community coalitions to work with local youth, parent, business, religious, civic, and other groups to help prevent youth substance use. Grants awarded through the DFC program are intended to support established community-based coalitions capable of effecting community-level change. All DFC-funded grantees are required to collect and report data on past 30-day use; perception of risk or harm of use; perception of parental disapproval of use; and perception of peer disapproval of use for four substances, including prescription drugs.

The second pillar of the Administration's *Plan* focuses on improving the operations and functionality of state-administered Prescription Drug Monitoring Programs (PDMPs). PDMP data can help prescribers and pharmacists identify patients who may be at-risk for substance use disorders, overdose, or other significant health consequences of misusing prescription opioids. State regulatory and law enforcement agencies may also use this information to identify and prevent unsafe prescribing, doctor shopping, and other methods of diverting controlled substances. Aggregate data from PDMPs can also be used to track the impact of policy changes on prescribing rates. The Prescription Behavior Surveillance System, funded by CDC and FDA, is developing this surveillance capacity for PDMPs. Research also shows that PDMPs may have a role in reducing the rates of prescribing for opioid analgesics. For example, states where PDMPs are administered by a state health department showed especially positive results.³³

In 2006, only twenty states had PDMPs. Today, the District of Columbia has a law authorizing a PDMP, and forty-nine states have operational programs.³⁴ The state of Missouri stands alone in not authorizing a PDMP. However, its state Senate and state House have passed separate bills authorizing a state PDMP. We are cautiously optimistic that this means 2015 will be the year we can finally say we have a PDMP in every state. Today, Kentucky, New York, Tennessee, New Mexico, and Oklahoma all require prescribers to use their state's PDMP prior to prescribing in certain circumstances.³⁵ In Tennessee, where the requirement to check the PDMP went into effect in 2013, there was a drop in the rate of high utilizers of opioid pain relievers from the fourth quarter of 2011 to the fourth quarter of 2013.

Building upon this progress, the HHS Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA are working with state governments and private sector technology experts to integrate PDMPs with health information technology (health IT)

³² 21 CFR Part 1308 Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II. DEA. Final Rule. Available at <http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf>

³³ Brady, JE, Wunsch, H, Dimaggio, C, Lang, BH, Giglio, J, and Li, G. Prescription drug monitoring and dispensing of prescription opioids. *Public Health Reports* 2014, 129 (2): 139-47.

³⁴ National Alliance of Model State Drug Laws. (2014). Status of State Prescription Drug Monitoring Programs (PDMPs). Retrieved from <http://www.namsdl.org/library/16666FCC-65BE-F4BB-A2BBA44E1BC7031/>.

³⁵ Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2014 Report to the 108th Tennessee General Assembly, February 1, 2014. Page 5. Available at http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf Linked to 9-04-2014

systems such as electronic health records. Health IT integration will enable authorized healthcare providers to access PDMP data quickly and easily at the point of care. To date, SAMHSA has provided funding to sixteen states, and ONC has conducted thirteen pilots focused on integrating health IT systems with PDMPs. CDC is currently evaluating the 2012 SAMHSA grantees to identify best practices and determine the impact of the integration efforts.

The Department of Justice's (DOJ) Bureau of Justice Assistance (BJA) is also supporting expanded interstate sharing of PDMP data. Data sharing between states is especially important. Currently, at least thirty states have some ability to share data. In 2010, no states had any capacity for interstate data sharing. PDMP administrators are working to better integrate these systems into other health IT programs.

In FY 2014, BJA made fifteen site-based awards for states to implement or enhance a PDMP program or strategy to address non-medical prescription drug use, misuse and diversion within their communities. Since inception of the grant program in FY 2002, grants have been awarded to forty-nine different states and one U.S. territory. The program allows for state discretion to accommodate local decision-making based on state laws and preference, while encouraging the replication of demonstrated best practices. In recent years, the grant program included tribal participation, and gave support to states and localities to expand collaborative efforts between public health and public safety professionals. For example, Maryland used the funding to form overdose fatality review (OFR) teams comprised of multi-agency, multi-disciplinary stakeholders who review information on individuals who died from drug and alcohol related overdose. The OFR teams meet monthly to review medical examiner and other data. They identify overdose risk factors, missed opportunities for prevention/intervention, and make policy recommendations.³⁶

In February 2013, the Department of Veterans Affairs (VA) issued an Interim Final Rule authorizing VA physicians to access state PDMPs in accordance with state laws and to develop mechanisms to begin sharing VA prescribing data with state PDMPs. The interim rule became final on March 14, 2014.³⁷ Since then, the VA has developed and installed software to enable VA pharmacies to transmit their data to PDMPs. As of April 2015, 67 VA facilities were sharing information with PDMPs in their respective states. VA providers have also begun registering and checking the state databases. However, VA's Veterans Health Administration (VHA) does not currently require prescribers to check the PDMP prior to prescribing. Investment in the VHA Electronic Health Record System is needed to expand PDMP integration.

While PDMP reporting is not required by IHS facilities, many tribes have declared a public health emergency and have elected to participate with the PDMP reporting initiative. Currently, IHS is sharing its pharmacy data with PDMPs in 18 states,³⁸ and IHS is in the process

³⁶ Maryland Department of Health & Mental Hygiene. (2014). Overdose Fatality Review in Maryland. Harold Rogers PDMP National Meeting. Retrieved from http://www.pdmpassist.org/pdf/PPTs/National2014/2-04_Baier.pdf. Linked to on 4-22-2015

³⁷ Disclosures to Participate in State Prescription Drug Monitoring Programs, 78 Fed. Reg. 9589 (Feb. 11, 2013); 79 Fed. Reg. 14400 (Mar. 14, 2014).

³⁸ Indian Health Service. (2014). Prescription Drug Monitoring Programs: Indian Health Service Update. Harold Rogers PDMP Annual Meeting. Retrieved from http://www.pdmpassist.org/pdf/PPTs/National2014/2-14_Tuttle.pdf.

of negotiating data-sharing with more states.³⁹ As these systems continue to mature, PDMPs can enable health care providers and law enforcement agencies to prevent the non-medical use and diversion of prescription opioids.

The third pillar of our *Plan* focuses on safely removing millions of pounds of expired and unneeded medications from circulation. Research shows that approximately 70 percent of past year nonmedical users of prescription pain relievers report getting them from a friend or relative the last time they used them, and approximately 84 percent of the time, that friend or relative obtained the pain relievers from one doctor.⁴⁰ Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner.

From September 2010 through September 2014, the DEA partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold nine National Take-Back Days. Through these events, DEA collected and safely disposed of more than 4.8 million pounds of unneeded or expired medications.⁴¹ The final National Take-Back Day took place on September 27, 2014. However, in September 2014, DEA published its Final Rule for the Disposal of Controlled Substances, which took effect October 9, 2014. These new regulations expand the options available to securely and safely dispose of unneeded prescription medications. They authorize certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. Collectors may operate a collection receptacle at their registered location, and anyone can distribute pre-printed/pre-addressed mail-back packages that go to mail-back program operators. Retail pharmacies and hospitals/clinics with on-site pharmacies may operate their own disposal collection receptacles. In addition, long-term care facilities that offer disposal collection receptacles must partner with either a retail pharmacy or a hospital/clinic with an on-site pharmacy to operate collection receptacles in their facilities. Any person or entity may partner with law enforcement to conduct take-back events. Additionally, VHA has agreed to offer drug take back at VA facilities for patients and those accompanying them to appointments.⁴²

ONDCP and DEA have engaged with Federal, state, and local agencies, and other stakeholders to increase awareness and educate the public about the new rule. In November 2014, ONDCP, DEA and the Alameda County California Superintendent's office hosted a webinar for community agencies to explain the new rule and discuss how local ordinances might

³⁹ Cynthia Gunderson, Prescription Drug Monitoring Programs & Indian Health Service, Barriers, Participation, and Future Initiatives, Presentation at Third Party Payer Meeting, December 2012. <http://www.pdmpeccence.org/sites/all/pdfs/Gunderson.pdf>

⁴⁰ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*. Department of Health and Human Services. [September 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm#2.16>

⁴¹ Drug Enforcement Administration. "DEA and Partners Collect 309 Tons of Pounds on Ninth Prescription Drug Take-Back Day." Department of Justice. [November 5, 2014]. Available: <http://www.dea.gov/divisions/hq/2014/ha110514.shtml>

⁴² Veterans Health Administration. "Joint Fact Sheet: DoD and VA Take New Steps to Support the Mental Health Needs of Service Members and Veterans." [August 26, 2014]. Available at: <http://www.va.gov/opa/docs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf> linked to on 12-01-2014.

define or fund disposal programs. Over 800 people registered for the program, and 436 viewed it live.⁴³ ONDCP, the Environmental Protection Agency, DEA, and HHS will continue to develop and implement a plan for engaging communities to increase safe disposal.

The *Plan's* fourth pillar focuses on improving law enforcement capabilities to reduce diversion of prescription opioids. Federal law enforcement is partnering with state and local agencies across the country to reduce pill mills and prosecute those responsible for improper or illegal prescribing practices. The National Methamphetamine and Pharmaceuticals Initiative (NMPI), funded through ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program, provides critical training on pharmaceutical crime investigations to law enforcement agencies across the country.

U.S. Customs and Border Protection, through its Laboratories and Scientific Service Directorate, routinely evaluates the type, volume, and quality of declared pharmaceutical products being shipped in international mail packages to guard against trafficking through the mail and parcel services. "Operation Safeguard" includes participation from numerous agencies, including the U.S. Postal Inspection Service, FDA, and DEA, and operates at international mail facilities.

All of these efforts under the *Prescription Drug Abuse Prevention Plan* are intended to reduce the diversion, non-medical use, and health and safety consequences of prescription opioids. The Administration has worked tirelessly to address the problem at the source and at an array of intervention points. This work has been paralleled by efforts to address heroin trafficking and use, as well as the larger opioid overdose problem facing this country. Just this week the Administration held its inaugural meeting of the Congressionally-mandated interagency Heroin Task Force. This Task Force is co-chaired by ONDCP Deputy Director for State, Local and Tribal Affairs Mary Lou Leary and U.S. Attorney for the Western District of Pennsylvania David Hickton, and includes Federal agency experts from law enforcement, medicine, public health and education. The Task Force will take an evidence-based approach to reducing heroin use and the public safety and public health consequences caused by heroin and prescription opioids.

The Administration continues to focus on vulnerable populations affected by opioids, including pregnant women and their newborns. Research suggests that over the last decade the prevalence of pregnant women using prescription medications may have increased.⁴⁴ From 2000 to 2009 the number of infants displaying symptoms of drug withdrawal after birth, known as neonatal abstinence syndrome (NAS), increased approximately threefold nationwide.⁴⁵

⁴³ Office of National Drug Control Policy. "Website Blog Watch: Webinar DEA Final Rule on Disposal of Controlled Substances." Available at: <https://www.whitehouse.gov/blog/2014/11/17/watch-webinar-dea-s-final-rule-disposal-control-substances>. Linked to on 4-15-2015

⁴⁴ Creanga, A.A., Sabel, J.C., Ko, J.Y., Wasserman, C.R., Shapiro-Mendoza, C.K., Taylor, P., Barfield, W., Cawthon, L., & Paulozzi, L.J. (2012). Maternal drug use and its effect on neonates: A population-based study in Washington State. *Obstetric Gynecology*, 119(5): 924-33. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22525903>.

⁴⁵ Epstein, R.A., Bobo, W.V., Martin, P.R., Morrow, J.A., Wang, W., Chandrasekhar, R., & Cooper, W.O. (2013). Increasing pregnancy-related use of prescribed opioid analgesics. *Annals of Epidemiology*, 23(8): 498-503. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/23889859>.

Newborns with NAS have more complicated and longer initial hospitalizations than other newborns.⁴⁶ Newly published data shows the problem nearly doubled from 2009 to 2012.⁴⁷ Moreover, 80 percent of the cost for caring for these infants was the responsibility of state Medicaid programs during this time.

In 2012, the Administration held a symposium of key stakeholders and researchers aimed at improving outcomes for opioid dependent women and their newborns. From this symposium, partnerships developed around the country focused on this emerging issue, including partnerships with the National Governor's Association and the Association of State and Territorial Health Officials. In 2013, ONDCP worked with the Vermont Oxford Network to improve care for mothers and infants affected by opioid dependence. The Network's multidisciplinary effort involves teams from 205 hospitals from 42 states, Canada, Ireland, and the United Kingdom. This ambitious project aims to improve every aspect of care delivered to families – from standardizing newborn treatment, to engaging community partners at the local level. ONDCP and its interagency partners have identified five action items to address NAS that HHS and ONDCP intend to work on in the final years of the Administration.

The Administration is focusing on several key areas to reduce and prevent opioid overdoses, including educating the public about overdose risks and interventions; increasing access to naloxone, an emergency opioid overdose reversal medication; and working with states to promote Good Samaritan laws and other measures that can help save lives. With the recent rise in overdose deaths across the country, it is increasingly important to prevent overdoses and make antidotes available.

The Administration is providing tools to local communities to empower them to save lives. In August 2013, SAMHSA released the *Opioid Overdose Prevention Toolkit*.⁴⁸ This toolkit provides communities and local governments with material to develop policies and practices to help prevent opioid-related overdoses and deaths. It contains information for first responders, treatment providers, and those recovering from opioid overdose. This kit will enable state and community leaders to implement effective overdose prevention initiatives and connect people to the treatment they need.

In July 2014, the Attorney General issued a Memorandum urging Federal law enforcement agencies to identify, train and equip personnel who may interact with victims of an opioid overdose.⁴⁹ In October 2014, Attorney General Holder announced the launch of the

⁴⁶ Patrick, S., Schumacher, R.E., Benneyworth, B.D., Krans, E.E., McAllister, J.M., & Davis, M.M. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. *Journal of the American Medical Association*, 307(18): 1934-40. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22546608>.

⁴⁷ Patrick, SW, Davis, MM, Lehman, CU, Cooper, WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012. *Journal of Perinatology* (2015): 1-6 online publication, April 30, 2015; doi:10.1038/jp.2015.36.

⁴⁸ Substance Abuse and Mental Health Services Administration. Opioid Overdose Prevention Toolkit. Department of Health and Human Services. [August 2013]. Available: <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>

⁴⁹ Department of Justice, Office of Public Affairs. "Attorney General Holder Announces Plans for Federal Law Enforcement Personnel to Begin Carrying Naloxone." [July 31, 2014]. Available at <http://www.justice.gov/opa/pr/attorney-general-holder-announces-plans-federal-law-enforcement-personnel-begin-carrying-linked-to-10-18-2014>

Department of Justice's *Naloxone Toolkit* for law enforcement.⁵⁰ This toolkit is an online clearinghouse of more than 80 resources, such as sample policies and training materials designed to support law enforcement agencies in establishing a naloxone program. Training and technical assistance may also be requested through the toolkit. And in August 2014, the Administration announced that DoD was making a new commitment to ensure that opiate overdose reversal kits and training are available to every first responder on military bases or other areas under DoD's control.⁵¹

The Administration continues to promote the use of naloxone by those likely to encounter overdose victims and be in the position to reverse the overdose, especially first responders and caregivers. Increasing access to naloxone is one of the priority areas of HHS opioid initiative, and the Administration's FY 2016 Budget requests \$12 million in grants to be issued by SAMHSA to states to purchase naloxone, equip first responders in high-risk communities, and provide education and the necessary materials to assemble overdose kits, as well as cover expenses incurred from dissemination efforts. Profiled in the 2013 *National Drug Control Strategy*, the Police Department in Quincy, Massachusetts, has partnered with the State health department to train and equip police officers to resuscitate overdose victims using naloxone. The Department reports that since October 2010, officers in Quincy have administered naloxone in more than 382 overdose events, resulting in 360 successful overdose reversals.⁵² In the past year, we have witnessed an exponential expansion in the number of police departments that are training and equipping their police officers with naloxone. They now number in the hundreds.

There is extraordinary collaboration taking place in rural and suburban communities such as Lake County, Illinois. As part of the Lake County Heroin/Opioid Prevention Taskforce, the Lake County State's Attorney has partnered with various county agencies, including the Lake County Health Department; drug courts; police and fire departments; health, advocacy and prevention organizations; and local pharmacies to develop and implement an opioid overdose prevention plan.⁵³ Since July 2014, the Lake County Health Department has trained more than 34 police departments, 27 of which are carrying naloxone. As of February 2015, the Lake County Health Department had trained 828 police officers and 200 sheriff's deputies to carry and administer naloxone, and more departments have requested this training.⁵⁴

Prior to 2012, just six states had any laws which expanded access to naloxone or limited criminal liability. Today, 35 states⁵⁵ and the District of Columbia have passed laws that offer criminal and/or civil liability protections to lay persons or first responders who administer naloxone. Twenty-four states⁵⁶ have passed laws that offer criminal and/or civil liability

⁵⁰ Department of Justice, Office of Public Affairs. "Remarks by Attorney General Holder at the International Association of Chiefs of Police Annual Conference." [October 27, 2014]. Available at: <http://www.justice.gov/opa/speech/remarks-attorney-general-holder-international-association-chiefs-police-annual-conference>

⁵¹ <http://www.va.gov/opa/docs/26-AUG-JOINT-FACT-SHEET-FINAL.pdf>

⁵² Quincy (Massachusetts) Police Department Reporting. Email received 3/15/15.

⁵³ Office of the State's Attorney, Lake County, Illinois, Michael G. Nerheim. "Call to Action Lake County Opioid Prevention Initiative." [May 29, 2013]. Available at: <http://lcsao.org/news/press-releases>

⁵⁴ Lake County Health Department Reporting. Email 2/19/15.

⁵⁵ CA, CO, ID, OR, UT, WA, AZ, NM, OK, GA, KY, LA, MS, NC, TN, VA, WV, CT, DE, MA, MD, ME, NJ, NY, PA, RI, VT, IL, IN, MI, MN, MO, OH, SD, and WI.

⁵⁶ CA, CO, ID, UT, AZ, NM, GA, MS, NC, TN, VA, WV, CT, MA, NJ, NY, PA, VT, IN, MI, MN, OH, SD, and WI.

protections for prescribing or distributing naloxone. Thirty-three states⁵⁷ have passed laws allowing naloxone distribution to third-parties or first responders via direct prescription or standing order. ONDCP is collaborating with state health and law enforcement officials to promote best practices and connect officials interested in starting their own naloxone programs. The odds of surviving an overdose, much like the odds of surviving a heart attack, depend on how quickly the victim receives treatment. Twenty-five states⁵⁸ and the District of Columbia have passed laws which offer protections from charge or prosecution for possession of a controlled substance and/or paraphernalia if the person seeks emergency assistance for someone that is experiencing an opioid induced overdose. As these laws are implemented, the Administration will carefully monitor their effect on public health and public safety.

The Affordable Care Act and Federal parity laws are extending access to mental health and substance use disorder benefits for an estimated 62 million Americans.⁵⁹ This represents the largest expansion of treatment access in a generation and could help guide millions into successful recovery. The President's FY 2016 budget request includes \$11 billion for treatment, a nearly seven percent increase over the FY 2015 funding level.

We are also seeking to ensure that the treatment people receive for their opioid use disorder is evidence-based. When combined with other supports, under the care of a physician, medication-assisted treatment (MAT) has been shown to be the best course of treatment for persons with an opioid use disorder. Several FDA-approved medications, including methadone, buprenorphine, and naltrexone, are proven treatment tools that are helping thousands of people maintain long-term recovery and lead healthy, productive lives. Additionally, medication assisted treatment may help reduce deaths from opioid drugs; a study found, for example, that increased access to medication-assisted treatment in Baltimore, Maryland, was associated with a reduction in heroin deaths.⁶⁰

It is essential to identify and engage people who use prescription opioids non-medically early because the risks of being infected with HIV or hepatitis C increases dramatically once someone transitions to injection drug use. In fact, just a few weeks ago, the state of Indiana and the CDC identified over 130 people in a small county in Indiana who tested positive for HIV.⁶¹ Many of these people had a history of injecting extended release oxymorphone. It is much less expensive to treat a person for just a substance use disorder early using evidence-based treatment, rather than to treat a person with a substance use disorder and provide lifetime treatment for HIV or a cure for hepatitis C.

⁵⁷ CA, CO, ID, OR, UT, WA, AZ, OK, GA, KY, LA, MS, NC, TN, VA, WV, CT, DE, MA, MD, ME, NJ, NY, PA, VT, IL, IN, MI, MN, MO, OH, SD, and WI.

⁵⁸ AK, CA, CO, UT, WA, NM, FL, GA, KY, LA, NC, WV, CT, DE, MA, MD, NJ, NY, PA, RI, VT, IL, IN, MN, and WI.

⁵⁹ Berino, K., Rosa, P., Skopec, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief*. Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm)

⁶⁰ Schwartz, RP, Gryczynski, J, O'Grady, KE, Scharfstein, JM, Warren, G, Olsen, Y, Mitchell, SG, and Jaffe, JH. Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009 *Am J Public Health*. 2013;103:917–922.

⁶¹http://www.in.gov/isdh/files/April_17_MORE_HIV_CASES_REPORTED_IN_SOUTHEASTERN_INDIANA_AS_TESTING_RAMPS_UP.pdf

Medication-assisted treatment should be the recognized standard of care for opioid use disorders. Research shows that even heroin users can sustain recovery if treated with evidence-based methods. Studies have shown that individuals with opioid use disorders have better outcomes with maintenance MAT.⁶² Yet for too many people, it is out of reach. For instance, in 2012 only 8 percent (1,167) of treatment facilities certified by SAMHSA provided treatment with methadone and/or buprenorphine (Opioid Treatment Programs).⁶³ Treatment programs are too often unable to provide this standard of care, and there is a significant need for medical professionals who can provide MAT in an integrated health care setting.

Medicines for opioid use disorder containing buprenorphine are an important advance that have only been available since Congress passed the Drug Addiction Treatment Act of 2000. They expand the reach of treatment beyond the limited number of heavily regulated Opioid Treatment Programs. Also because physicians who have taken the training to administer the medicines are allowed to treat patients in an office-based setting, it allows patient care to be integrated with mainstream medicine. Injectable naltrexone offers similar advantages but only to patients who have been abstinent for 7-10 days. Special training is not required for injectable naltrexone and its use is not limited to physicians.

We need to increase the number of physicians who can prescribe buprenorphine, when appropriate and the numbers of providers offering injectable naltrexone. Of the more than 877,000 physicians who can write controlled substance prescriptions, only about 29,194 have received a waiver to prescribe office-based buprenorphine. Of those, 9,011 had completed the requirements to serve up to 100 patients. The remainder can serve up to 30. Although they were augmented by an additional 1,372 narcotic treatment programs, far too few providers elect to use any form of medication-assisted treatment for their patients.⁶⁴ Injectable naltrexone was only approved for use with opioid use disorders in 2012, and little is known about its adoption outside specialty substance use treatment programs but use in primary care and other settings are possible. To date only about 3% of U.S. treatment programs offer this medicine for opioid use disorder.⁶⁵ Education on the etiology of opioid abuse and clinician interventions is critical to increasing access to treatments that will stem the tide of abuse and overdose.

The Administration is committed to promoting MAT in treatment systems at the Federal, state, and local levels. Increasing access to MAT is another one of the priority areas of the HHS opioid initiative. The President's FY 2016 budget request includes: an additional \$26 million (\$60 million total) within the total for the Second Chance Act grant for substance use treatment to help reduce re-offending and violations of probation and parole; an additional \$13.1 million (\$25.1 million total) for SAMHSA to expand MAT for its Prescription Drug and Opioid Addiction program; \$5 million for the Agency for Healthcare Research and Quality to provide a

⁶² Weiss RD, Potter JS, Griffin ML, McHugh RK, Haller D, Jacobs P, Gardin J 2nd, Fischer D, Rosen KD. Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial Published in final edited form as: Arch Gen Psychiatry. 2011 December; 68(12): 1238–1246.

⁶³ SAMHSA. *National Survey of Substance Abuse Treatment Services (N-SSATS): 2012 -- Data on Substance Abuse Treatment Facilities* (December 2013).

⁶⁴ Personal communication (email) from Robert Hill (DEA).

⁶⁵ Aletraris LI, Bond Edmond M1, Roman PM1.. Adoption of injectable naltrexone in U.S. substance use disorder treatment programs. J Stud Alcohol Drugs. 2015 Jan;76(1):143-51.

more robust review of evidence and evaluation regarding MAT in primary care settings as well as grants to develop and test new methods, processes, and tools for better implementing these treatment strategies; and an additional \$1.2 million (\$116.6 million total) for the Bureau of Prisons' substance use disorder treatment program and \$1 million to expand its MAT field trial.

Reducing and preventing opioid diversion, abuse, overdose, and the array of public health and safety consequences requires collaboration with a broad range of stakeholders. The Administration has worked closely with a number of associations and groups, including the National Governors Association, the National Association of Attorneys General, the American Medical Association, the American Dental Association, the American College of Emergency Physicians, the National Safety Council, the National Conference of State Legislatures, the National Association of Boards of Pharmacy, the Association of State and Territorial Health Officials, state medical boards, and countless community groups in states, localities, and tribes across the country. All of these groups and the constituencies they represent have recognized the urgency of this national problem and are helping to bring about the changes we need to prevent negative health consequences like transmission of infection, and more deaths as well as to protect the public safety through targeted enforcement and smart on crime approaches that decrease diversion of prescription opioids and reduce the supply of heroin.

And there are some signs that these national efforts are working. The number of Americans 12 and older initiating the nonmedical use of prescription opioids in the past year has decreased significantly since 2009, from 2.2 million in that year to 1.5 million in 2013.⁶⁶ Additionally, according to the latest Monitoring the Future survey, the rate of past year use among high school seniors of OxyContin or Vicodin in 2014 is its lowest since 2002.⁶⁷

However, while all of these trends are promising, the national data cited earlier concerning increases in emergency department visits, treatment admissions, and overdoses involving opioids bring the task ahead of us into stark focus. Continuing challenges with prescription opioids, and concerns about a reemergence of heroin use, particularly among young adults, underscore the need for leadership at all levels of government.

Conclusion

We continue to work with our Federal, state, local, and tribal partners to continue to reduce and prevent the health and safety consequences of nonmedical prescription opioid and heroin use. Together with all of you, we are committed partners, working to reduce the prevalence of substance use disorders through prevention, increasing access to treatment, and helping individuals recover from the disease of addiction. Thank you for the opportunity to testify here today, and for your ongoing commitment to this issue. I look forward to continuing to work with you on this pressing public health matter.

⁶⁶ Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7pcTabs1to45-2013.htm#tab7.36A>

⁶⁷ The Monitoring the Future study. *Narcotics other than Heroin: Trends in Annual Use and Availability – Grades 8, 10, and 12*. University of Michigan. [December 2014]. Available: <http://www.monitoringthefuture.org/data/14data/14drfig11.pdf>

Mr. MURPHY. Thank you.

Dr. Frank, we're going to try and get your testimony and then we're going to run off and vote, and we'll be back. Go ahead.

STATEMENT OF RICHARD G. FRANK

Dr. FRANK. OK. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for the opportunity to discuss how the Department of Health and Human Services is addressing the opioid abuse epidemic.

Containing the abuse and misuse of prescription opioids and heroin is a high priority for the HHS leadership team, and we're pleased to be here with you today. I would like to use my time today to give you an overview of how we view the challenge and describe how we are working to develop a multifaceted solution to this problem. It's going to take a lot of collaboration, and we are pleased to work with you and other stakeholders on this issue.

Addiction to and abuse of opioids, including both prescription painkillers and heroin and the terrible outcomes associated with them, are growing at an alarming pace. Just over a third of drug overdose deaths in 2012 and 2013 were from prescription opioids, while heroin-related deaths have spiked dramatically, almost tripling since 2010.

The sharp increase in the misuse and abuse of opioids places a great burden on the health system. There were 259 million prescriptions filled for opioids in the U.S. in 2012, a large increase over just a few years prior. The Medicare program under part D spent \$2.7 billion on opioids overall in 2011, 1.9 billion of that total, or 69 percent was accounted for by the top 5 percent of opioid users. Those spending patterns on these drugs reflect some of our concerns.

The cost of abuse and misuse of opioids shows up in preventable use of very expensive health care. Heroin presents an equally troubling, but different abuse and overdose pattern. We saw increases between 2002 and 2009 in a number of people using heroin, but that number has held fairly steady since 2009.

The striking new trend is that there's an increasing share of the users that are dying from heroin overdoses. So what I'm telling you is that we have a opioid prescribing problem, sitting alongside a drug abuse and misuse problem.

Secretary Burwell is committed to aggressively addressing the epidemic. She's driving us towards two main goals: One, reducing opioid overdoses and overdose-related mortality; and two, decreasing the prevalence of opioid use disorder. She directed us to use the best science and to focus on the most promising levers that can make a difference for the people who struggle with opioid addiction and their families.

HHS agencies have been collaborating on this problem for some time, and we hope you will agree after today that the whole is greater than the sum of the parts.

Our actions informed by the evidence and discussions with States and other stakeholders fall into three general categories: One, addressing opioid prescribing practices; two, expending the use of naloxone; and three, promoting medication-assisted treatment.

Let me outline the plan in a bit more detail. First, PDMPs. We're increasing investments in prescription drug monitoring programs, which are among the most promising clinical tools to curb prescription opioid abuse. We're investing it through State grants and technical assistance and supporting best practices to maximize the impacts of PDMPs.

Second, naloxone, which is the life-saving drug that can reverse overdose from both prescription opioids and heroin. We're supporting the development of user-friendly formulations and delivery mechanisms and are working with State and local governments to support training and other measures that get naloxone into the hands of those that are in a position to reverse overdoses.

Finally, we have plans to support the appropriate use of medication-assisted treatment, or MAT. The enactment of the Mental Health Parity and Addiction Act opens up new opportunities to expand access to these evidence-based treatments.

We are also working on identifying best practices in primary care settings, increasing access to MAT through SAMHSA grant support and potentially increasing the supply of MAT providers by reviewing the policy and regulations that limit the types of individuals certified to prescribe. Our commitment to halting this complex public health epidemic is set out in the President's 2016 budget that includes a \$99 million increase for parts of our initiative.

Finally, evaluation will help us identify the most effective activities, allow us to continuously learn, and inform future policy making in order to address this public health concern.

So, in closing, this is critical for HHS and for the Nation, and we can't do it alone. We need help. Thank you for encouraging an open discussion of this today, and we are committed to turning the tide on this scourge that has become the opioid epidemic.

[The prepared statement of Mr. Frank follows:]



Testimony
of
Richard G. Frank, PhD
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

Before the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

May 1, 2015

Chairman Murphy, Ranking Member DeGette and members of the Subcommittee, thank you for this opportunity to discuss how the Department of Health and Human Services (HHS) is addressing the opioid abuse epidemic. Containing and eliminating the abuse of prescription opioids and heroin is a high priority for HHS and for Secretary Sylvia Mathews Burwell, and we are pleased to be here with you today to discuss this issue. This is also a critical issue for the Administration. In addition to the substantial expansion of substance abuse coverage through the Affordable Care Act and the implementation of mental health and substance abuse parity protections, the President's FY 2016 Budget proposes critical investments to intensify efforts to reduce opioid misuse and abuse, including \$133 million in new funding.

I would like to use my time today to talk about how we at HHS view the challenge and describe how we are working to develop a multifaceted solution for this complex problem. It is going to take a lot of collaboration across partners, agencies, and the Congress to make progress, and you will be hearing from many of those partners today.

Trends In Opioid Use and Abuse, Injury and Death

The United States is experiencing alarming trends in consequences stemming from the abuse of and addiction to opioids. Drug overdose deaths have been increasing over the past two decades and, in 2009, became the leading cause of injury death in the United States.¹ Approximately 37 percent of drug overdose deaths in 2013 involved prescription opioids, a number that has remained essentially unchanged from 2012. During this time the initiation of heroin use has grown modestly but mortality from heroin has spiked dramatically² – nearly tripling since 2010. Heroin overdose deaths increased by 39 percent from 2012 to 2013 alone, and accounted for about 19 percent of all drug overdose deaths in 2013.³

The highest use, highest risk nonmedical users of prescription pain medications obtain them from their physicians.⁴ These medications have an important place in treating pain, but it is easy to become addicted to them. Chronic nonmedical use, or nonmedical use of 200 days or more in the past year, increased by roughly 75 percent between 2002-2003 and 2009-2010.⁵ Prescription opioids taken with other misused or abused prescription drugs such as benzodiazepines (e.g. sedatives like Xanax) and antidepressants are also commonly linked to overdose deaths.⁶

¹ Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS), 2014. Available at <http://www.cdc.gov/injury/wisqars/fatal.html>

² Rachel N. Lipari, Ph.D., and Arthur Hughes, MS. "Trends in Heroin Use in the United States: 2002 to 2013." Substance Abuse and Mental Health Services Administration. April 23, 2015. Available at http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.html

³ Hedegaard H, Chen LH, Warner M.; National Center for Health Statistics (NCHS). Drug-poisoning deaths involving heroin: States, 2000–2013. NCHS data brief, no190. Available at <http://www.cdc.gov/nchs/data/databriefs/db190.pdf>

⁴ Jones CM, Paulozzi LJ, Mack KA. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use United States, 2008-2011. JAMA Intern Med. 2014 May;174(5):802-3.

⁵ Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267

⁶ Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. JAMA. 2013 Feb 20;309(7):657-9

Existing evidence shows that individuals at greatest risk for prescription opioid overdose include:⁷

- People living in rural areas and having low income
- People with mental illness or history of alcohol or other substance abuse
- People who obtain multiple controlled substance prescriptions (especially the combination of opioid analgesics and benzodiazepines) from multiple providers
- People receiving high daily dosages of opioid pain relievers

Death from heroin overdose follows a somewhat different pattern. Deaths involving heroin increased across the country, but an analysis by the Centers for Disease Control and Prevention (CDC) shows heroin overdose death rates in 2013⁸ highest among:

- Adults aged 25-44 years old
- White, non-Hispanic people
- Men
- People living in the Northeast and Midwest

Opioid Prescribing Patterns and the Burden on the Health Care System

There were 259 million prescriptions written for opioids in the U.S. in 2012, a large increase from just a few years ago,⁹ and Americans' use of prescription drugs has increased over the past half century. The increase is related to many factors, including a corresponding increase in insurance coverage for these drugs.¹⁰ For example, the Medicare program (through Part D, implemented in 2006) spent \$2.7 billion on opioids overall in 2011, and \$1.9 billion of that total (69 percent) was accounted for by the top five percent of opioid users.¹¹ These data are consistent with the trend showing a sharp increase in nonmedical use of prescription pain relievers by a relatively small number of "heavy users."¹² It is vital that we balance combatting abuse with supporting health care providers in making the best clinical recommendations for their patients' pain management.

In addition to the tragic consequences of opioid abuse on families and communities, this epidemic is a drain on the Nation's health care system. The growth in abuse and misuse of these drugs is costly in terms of claims made on health care resources. For example, rates of

⁷ Risk Factors for Prescription Painkiller Abuse and Overdose. Centers for Disease Control and Prevention. Accessed April 2015. Available at <http://www.cdc.gov/drugoverdose/epidemic/riskfactors.html>.

⁸ Hedegaard, Holly, Chen, Li-Hui, and Warner, Margaret. Drug-poisoning Deaths Involving Heroin: United States, 2000-2013. NCHS Data Brief No. 190, March 2015. Available at <http://www.cdc.gov/nchs/data/databriefs/db190.pdf>.

⁹ Vital Signs: Opioid Painkiller Prescribing. Centers for Disease Control and Prevention, July 2014. Available at <http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf>.

¹⁰ National Center for Health Statistics. Health, United States, 2013: With Special Feature on Prescription Drugs. Hyattsville, MD. 2014. Available at <http://www.cdc.gov/nchs/data/hus/hus13.pdf>.

¹¹ Suzuki, Shinobu. Potentially Inappropriate Opioid Use in Medicare Part D. MEDPAC. October 9, 2014. Available at <http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-pdf?sfvrsn=0>

¹² Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267

emergency department visits linked to misuse or abuse of pharmaceuticals increased 114 percent between 2004 and 2011: in 2011, more than 1.4 million emergency-department visits were due to the misuse or abuse of pharmaceuticals, with 420,000 involving prescription opioids and 425,000 involving benzodiazepines.¹³

Heroin Patterns

Heroin presents an equally troubling, but different use and overdose pattern. Recent estimates from the Substance Abuse and Mental Health Services Administration (SAMHSA) show increases between 2002 and 2009 in the number of people using heroin, but that number has held fairly steady since 2009 (in 2013 it was 681,000 past-year users).¹⁴ At the same time, deaths from heroin overdoses are increasing rapidly. Somewhat more encouraging are reports indicating that the numbers of people receiving treatment for heroin use has been increasing steadily since 2010.

Connections Between Pain Treatment, Prescription Opioids and Heroin

The media has reported extensively on the relationship between pain treatment, prescription opioid abuse and heroin initiation. There are no clear paths, but the evidence points to some important associations. First, the majority – 75 percent – of heroin users began with a prescription for pain.¹⁵ Even when used appropriately, these drugs run the risk of being highly addictive.

Second, many heroin users report past-year non-medical use of prescription drugs. Between 2002–2004 and 2008–2010, past-year heroin use increased among people reporting non-medical use of prescription opioids within the past year, but not among those reporting no non-medical use in the past year.¹⁶ This stands in stark contrast to the heroin problem of the 1960s; although strong pain medications existed at the time, eight out of ten of the people who initiated opioid use in that decade began their opioid use with heroin.¹⁷

Third, although most heroin users report past-year non-medical use of pain medications, the evidence does not show that non-medical prescription opioid use leads to heroin use in the majority of cases. Current estimates are that less than 4 percent of those who initiated initiate prescription opioid use non-medically go on to initiate heroin use.

¹³ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Available at <http://www.samhsa.gov/data/sites/default/files/DAWN127/DAWN127/sr127-DAWN-highlights.htm>

¹⁴ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. Available at <http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm>

¹⁵ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6.

¹⁶ Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010. *Drug Alcohol Depend* 2013;132:95–100

¹⁷ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6

Finally, heroin is easier and cheaper to get and to use these days, and its potency is much greater than many prescription opioids.¹⁸ For example, according to the Office of National Drug Control Policy, the price per pure gram of heroin purchased at the “retail level” (10 grams or less) has dropped over the past few years, from \$595 per pure gram in 2010 to \$465 per pure gram in 2012.¹⁹ This is a nearly 22 percent drop in the retail price of heroin. Like other products, reduced prices result in increased demand. Additionally, reports from Federal, state, and local law enforcement via the Drug Enforcement Administration indicate that the availability of heroin has increased across the country.

The HHS Approach to the Problem: Secretary’s Initiative

Secretary Burwell’s initiative is directly addressing the threat posed by opioids to the health of the American public and the costs imposed on public and private budgets. At her direction, we are taking steps where the evidence indicates we will have the greatest impact. We are focused on two clear outcomes: (1) reducing opioid overdoses and overdose-related mortality and (2) decreasing the prevalence of opioid use disorder.

To accomplish these clear but challenging goals, Secretary Burwell directed HHS senior leadership and staff from across the department to identify a focused set of actions using some basic decision rules:

- Include actions that the evidence indicates have a high likelihood of making a measurable difference.
- Aim to have an impact in the intermediate term, while establishing a platform for long-term effects.
- Make use of HHS’ most promising levers and partner with other stakeholders to make a difference for the people who struggle with opioid use disorder and their families.

The Agencies that you will be hearing from have been collaborating on this problem for some time through an Administration-wide effort by the White House Office of National Drug Control Policy, HHS’s Behavioral Health Coordinating Council, and through the Secretary’s meetings on her initiative. Specifically, the actions in the initiative that we all will tell you about are grounded in the best research and clinical science available.

The areas for action were identified through a Department-wide effort that tapped all the scientific, analytical, and programmatic expertise found at HHS; as well as discussions with states and other stakeholders.

The Secretary’s initiative includes actions in three priority areas to combat opioid abuse:

- Opioid prescribing practices to reduce opioid use disorders and overdose
- Expanded use and distribution of naloxone

¹⁸ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6

¹⁹ Office of National Drug Control Policy. National Drug Control Strategy: Data Supplement 2014, p. 81. Available at https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_data_supplement_2014.pdf

- Expansion of Medication-assisted Treatment (MAT) to reduce opioid use disorders and overdose

Taking Actions Based on Evidence of What Works

The efforts are grounded in the best available science. There is a growing body of research that supports the effectiveness of several interventions to address opioid abuse. Continued monitoring, evaluation, and research are essential to further strengthen the evidence base and inform program and policy decision-making. We have particularly targeted three important tools in this work. The first is Prescription Drug Monitoring Programs (PDMPs) because they enable us to track prescribing patterns and intervene and train to turn things around. The second tool is expanding access to naloxone, which can reverse the effects of both prescription opioid and heroin overdose. And the third tool is MAT, which involves the combination of medications and therapeutic supports to help people recover from opioid addiction.

Prescription Drug Monitoring Programs

Health care providers – prescribers – are on the front line and they are important allies in this effort. We are increasing investments in prescription drug monitoring programs (PDMPs), which are state-run electronic databases of prescriptions for controlled substances and are among the most promising clinical tools to curb prescription opioid abuse. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially abusing medications. The organization and operation of PDMPs varies among states. Different states have variations around how often the data are collected and reported, which state agency houses the PDMP, who is able to access it, and which controlled substances must be reported, among other variations.

Currently, 49 states, the District of Columbia, and one U.S. territory (Guam) have legislation authorizing the creation and operation of a PDMP and all but the DC program are operational.²⁰ We have seen promising steps taken by Missouri in the past few weeks to lay the ground work for a PDMP.

Existing evidence indicates the potential of PDMPs to identify high-risk patients and impact key prescribing behaviors.²¹ Evaluations of a selected group of PDMPs have detected positive changes in prescribing patterns, decreased use of multiple providers and pharmacies, and decreased substance abuse treatment admissions. For example, a preliminary analysis of the impact of laws mandating use of PDMPs by prescribers in Kentucky, Tennessee, and New York showed reductions in multiple provider episodes (e.g., approximately 75 percent decline in New York), a risk factor for opioid overdose. Controlled substance prescribing also declined in states

²⁰ PDMP Training and Technical Assistance Center. PDMP Frequently Asked Questions. Available at <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>

²¹ PDMP Center of Excellence at Brandeis University. Briefing on PDMP Effectiveness: Updated September 2014. Available at <http://www.pdmplexcellence.org/sites/all/pdfs/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf>

that mandated PDMP use (e.g., in Kentucky doses dispensed declined for hydrocodone by approximately 10 percent, oxycodone by 12 percent, and oxymorphone by 35 percent).²²

CDC and SAMHSA are providing grants to states to support development and use of PDMPs, and you will hear more about that from CDC and SAMHSA today.

Clinical decision support tools and health IT systems incorporating PDMP and other clinical data also show promise for improving prescribing behaviors and reducing adverse events.²³ As states work to adopt more evidence-based PDMP practices such as collecting data for all controlled substances, proactive reporting to physicians and pharmacists, interstate data sharing, and integration with other health IT systems to improve provider use, their effectiveness is likely to increase.²⁴

Guidelines

There is a clear correlation between opioid prescribing rates and overdose death rates in the United States. From 1999 to 2010, opioid prescribing quadrupled in parallel to increasing opioid overdose death rates.²⁵ These data underscore the importance of prescribing guidelines that encourage the use of opioids when benefits outweigh risks and that promote safe use when opioids are needed.

A recent study of workers compensation patients in Washington State found that after the introduction of voluntary opioid guidelines in 2007, there was a 27 percent decline in the mean dose for long-acting opioids, a 35 percent decline in the percentage of patients receiving 120 morphine milligram equivalents per day or more, and a 50 percent reduction in opioid-related overdose deaths among injured workers.²⁶ If followed and universally implemented, integrating guidelines into electronic health records or clinical decision support platforms may help to reduce inappropriate prescribing of drugs commonly involved in overdose deaths.

Naloxone

Naloxone is an effective drug that can reverse overdose from both prescription opioids and heroin. This drug saves lives. It can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of heroin or prescription opioid overdose. Many overdose education and naloxone distribution programs have been developed to issue naloxone

²² PDMP Center of Excellence at Brandeis University. COE Briefing—Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States. Available at http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf

²³ PDMP Center of Excellence at Brandeis University. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, September 2012. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

²⁴ PDMP Center of Excellence at Brandeis University. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, September 2012. Available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

²⁵ Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999–2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487–1492.

²⁶ Franklin GM, Mai J, Turner J, Sullivan M, Wickizer T, Fulton-Kehoe D. Bending the prescription opioid dosing and mortality curves: impact of the Washington State opioid dosing guideline. Am J Ind Med. 2012;55(4):325–31.

and provide instructions on its use to law enforcement officers, opioid users, their friends and loved ones, and other potential bystanders.

As of July 2014, 24 states have statutes that allow for “third-party” prescriptions of naloxone (*i.e.* the prescription can be written to friend, relative or person in a position to assist a person at risk of experiencing an opioid overdose).²⁷ An evaluation of Massachusetts’ overdose education and nasal naloxone distribution program, which trained potential overdose bystanders, found that opioid overdose death rates declined in communities where programs were implemented.²⁸ Given the effectiveness of naloxone in overdose reversal, the Food and Drug Administration (FDA) has encouraged innovations in more user-friendly naloxone delivery systems such as auto-injectors, made particularly for lay use outside of health care settings. FDA approved such an auto-injector in 2014.

Medication-assisted Treatment (MAT)

Studies have shown that the most effective treatments for opioid use disorders (including both prescription opioids and heroin) are those that include a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual.²⁹ MAT is the use of medications such as buprenorphine, methadone, and extended release naltrexone, among others, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of opioid use disorders.

MAT is a safe and effective strategy for decreasing the frequency and quantity of opioid use and reducing the risk of overdose and death.³⁰ Furthermore, recently published research indicates that the most prevalent forms of MAT, buprenorphine and methadone, are similar in terms of effectiveness.³¹ A recent National Quality Forum workshop found that many psychosocial treatments are effective (such as cognitive behavioral therapy, structured family therapy, and 12-step facilitation therapy, among others) for certain substance use disorders. However, that same workshop explicitly recommended that patients with opioid dependence be offered pharmacotherapy directly linked to psychosocial treatments.³² The evidence points to a

²⁷ State Naloxone and Good Samaritan Legislation. Office of National Drug Control Policy, August 2014. Available at https://www.whitehouse.gov/sites/default/files/ondcp/Blog/naloxonecirclechart_august2014.pdf.

²⁸ Walley AY, Xuan Z, Hackman HH, Quinn E, Doe-Simkins M, Sorensen-Alawad A, Ruiz S, Ozonoff A. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ*. 2013 Jan 30;346:f174. doi: 10.1136/bmj.f174

²⁹ Connerly, HS. Medication-assisted treatment of opioid use disorder: review of the evidence and future directions. *Harv Rev Psychiatry*. 2015 March-April;23(2):63-75. doi: 10.1097/HRP.0000000000000075. Available at <http://www.ncbi.nlm.nih.gov/pubmed/25747920>.

³⁰ National Institutes on Drug Abuse. Cost effectiveness of drug treatment. Retrieved from: <http://www.drugabuse.gov/publications/teaching-packets/understanding-drug-abuse-addiction/sectioniv/6-costeffectiveness-drug-treatment>

³¹ Potter, J.S.; Marino, E.N.; Hillhouse, M.P., et al. Buprenorphine/naloxone and methadone maintenance treatment outcomes for opioid analgesic, heroin, and combined users: findings from Starting Treatment with Agonist Replacement Therapies (START). *Journal of Studies on Alcohol and Drugs* 74(4):605-613, 2013

³² Power, Elaine J., Nishimi, Robyn Y., and Kizer, Kenneth W., Editors. National Quality Forum: Evidence-Based Treatment Practices for Substance Use Disorders, 2005. Available at http://www.apa.org/divisions/div50/doc/Evidence_Based_Treatment_Practices_for_Substance_Use_Disorders.pdf

combination of medication and psychosocial services. Using either of these two interventions alone is inconsistent with the evidence about what works best for opioid use disorders.

Although MAT has significant evidence to support it as an effective treatment, it remains highly underutilized, being used by only an estimated one million of the 2.5 million Americans who might benefit from receiving it.³³ The barriers to access to MAT are many and varied, including a lack of available prescribers, lack of support for existing prescribers, minimal counseling coverage, and workforce attitudes and misunderstandings about the nature and use of MAT.

With further research and investment in these areas, the Secretary's initiative will continue to build upon the evidence base for effective interventions and help reduce opioid related morbidity and mortality, while also balancing the need for effective and appropriate pain management for those who need it most.

Next Steps to Keeping People Healthy

HHS continues to address this complex public health epidemic. The FY 2016 President's Budget for HHS includes an increase of \$99 million above FY 2015 for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders. As I mentioned, and as you will hear from my HHS colleagues, across the Department, we are working to implement the Secretary's initiative by developing prescribing guidelines, investing in demonstration programs to expand medication-assisted treatment services, and expanding utilization of naloxone for individuals at risk of overdose via grant programs, among other key activities.

Additionally, the Office of the Assistant Secretary for Planning and Evaluation is conducting research to further inform best practices for opioid prescribing. For example, we are funding a project to examine the impact of changing the default prescription quantity when a physician enters an opioid prescription into an electronic health record. Most systems prepopulate the number of days prescribed with a 30-day prescription. To our knowledge, there is no evidence-based reason for this default quantity.

This summer, HHS is also convening the 50 states and Washington, D.C. in a two-day working meeting on best practices for states to address opioid abuse and addiction. We are working with stakeholders to ensure that the convening focuses on the biggest challenges for state policy makers in this area, and helps to elevate many of the potential solutions and best practices underway or under development across the country.

HHS has also prioritized the development of an evaluation strategy to identify the most effective activities and inform future policymaking in order to have the greatest public health impact. Evaluation is a critical component of the initiative to identify what works and how the most effective interventions can be taken to scale. HHS leadership has joined together to aggressively implement the new initiative and monitor progress. Many activities are already underway, and the Department continues to seek opportunities to work with its partners on this critical issue.

³³ Volkow ND1, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies--tackling the opioid-overdose epidemic. *N Engl J Med.* 2014 May 29;370(22):2063-6. doi: 10.1056/NEJMmp1402780. Epub 2014 Apr 23

Conclusion

This is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

Mr. MURPHY. Thank you, Doctor.

Now, for the members—so votes are in progress. And even though time is running out, just to let you know, I think only about 20 people voted so far. So, apparently, this is throwing everybody off in their schedules.

I apologize. This is what happens on Capitol Hill. But we're committed to hear from you. We know how important this is and we value your testimony. So we're probably going to be back in a little under an hour. So we look forward to hearing from you then and getting the rest of this testimony. Thank you.

[Recess.]

Mr. MURPHY. All right. Thank you for being patient.

All right. Dr. Volkow, you're recognized for 5 minutes.

STATEMENT OF NORA D. VOLKOW

Dr. VOLKOW. Good morning, Chairman Murphy, Ranking Member DeGette, and other members of the subcommittee. I want to thank you for organizing and inviting me to participate in this important hearing.

The nonmedical use of prescription pain relievers is a particular public health challenge, for it demands solutions, on the one hand, to prevent their diversion and misuse, while at the same time, it demands so many solutions that will not jeopardize access to these medications for those that need them.

Opiate medications are probably among the most effective pain-killers that we have for the management of acute severe pain, and the proper use can actually save lives. They act by activating opioid receptors that are located in the areas of the brain that perceive pain, but there are very high concentration of opioid receptors in brain reward regions, and hence, the problem. Activation of these receptors is what is associated with their addiction potential.

There are also high levels of receptors in areas of the brain that regulate breathing, which is why their use is associated also with a high risk of death from overdose.

We have heard the devastating consequences from the escalation of the abuse of prescription medications in our country, the overdose deaths and transition to injection of heroin and associated infections with HIV and hepatitis C, and increasing numbers that we are seeing for the neonatal abstinence syndrome.

NIDA's role in helping solve this epidemic is to support the research that will help develop solutions to prevent and treat abuse of prescription medications that could be implemented now, while, at the same time, funding research that in the future will provide transformative solutions.

There are already evidence-based practices that have been shown to be effective in the prevention of overdose death that include the use of medications for opioid addiction and the use of naloxone to reverse opioid overdoses.

There are three medications currently available to treat opioid addiction: methadone, buprenorphine, and naltrexone, which, when used as part of a comprehensive addiction treatment plan, have been shown to facilitate abstinence and reduce overdoses and HIV infections. Also, when coupled to prenatal care in pregnant women addicted to opioids, these medications reduce the risk of obstetrical

fetal and neonatal complications. Yet, despite the strong evidence, less than 40 percent of those receiving treatment for opioid addiction get treated with these medications. Toward this end, NIDA is funding research on implementation strategies that facilitate the use of medications for opioid addiction in the healthcare system.

Another key component to decrease the overdose deaths is to expand the use of naloxone, so NIDA has partnered with pharmaceutical companies to develop user-friendly, effective delivery systems for naloxone that will facilitate their use by those that have absolutely no medical training.

In addition, NIDA supports research on the treatment of pain and on the treatment of opioid addiction that will offer new solutions for the treatment of these two disorders. Examples for the management of pain include the development of drug combinations or new formulations with less addiction potential, the development of analgesics that do not rely on the opioid system, and the development of nonmedication interventions, such as the use of transcranial magnetic or electrical brain stimulation for pain management.

Examples of research on the treatment of opioid addiction include the development of slow-release formulations that need only once-a-month or once-every-6-months dosing—which will facilitate compliance and use—and the development of vaccines against heroin, which will prevent the delivery of the drug into the brain, hence, interfering with its rewarding effects and adverse consequences.

Because the epidemic of prescription drug abuse resulted from a lack of knowledge by healthcare providers, the importance of developing curriculum to train both in pain and in substance abuse disorders is another priority which NIDA has developed in partnership with the other institutes and NIH Centers of Excellence.

There were over 24,000 deaths from opioid overdoses in 2013. Twenty-four thousand. This highlights the urgency to address this epidemic. Solutions are already available. The challenge is the implementation. This requires strong integration of efforts, and NIDA will continue to work closely with other Federal agencies, community organizations, and private industries to address this complex challenge.

[The prepared statement of Dr. Volkow follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE

What Science Tells us About Opioid Abuse and Addiction

Testimony before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Nora D. Volkow, M.D.
Director, National Institute on Drug Abuse (NIDA)

May 1, 2015

Good Morning, Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee. Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this important hearing and provide an overview of what science tells us about the growing and intertwined problems of non-medical use of prescription pain medicines and use of heroin in our Nation.

Background

The misuse of and addiction to opioids such as heroin, morphine, and other prescription pain medicines is a serious national problem that affects public health as well as social and economic welfare. An estimated 1.9 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines in 2013 and 517,000 suffered from a heroin use disorder.¹ This issue has become a public health epidemic with devastating consequences including not just opioid use disorders and related overdoses, but also the rising incidence of newborns who experience neonatal abstinence syndrome because their mothers used these substances during pregnancy; and increased spread of infectious diseases including HIV and hepatitis C (HCV).

Existing evidence based prevention and treatment strategies are highly underutilized across the United States. The recently announced initiative of the Secretary of Health and Human Services to address the complex problem of prescription opioid and heroin abuse in this country emphasizes the implementation of these evidence based prevention and treatment strategies which include not only better prescription practices but also deployment of medication to combat overdoses and medication-assisted treatment (MAT) to treat opioid use disorders. NIDA is an active partner in this initiative and will focus on supporting research and disseminating findings to improve opioid prescribing practices, to expand the use of the opioid overdose reversal drug naloxone, to improve the integration of pharmacotherapies into treatment services in specialty care and primary care, and to develop pain treatments with reduced potential for misuse and diversion.

The Effects of Opioids on the Brain and Body

Both prescription opioid drugs (such as oxycodone and hydrocodone) and heroin work through the same mechanism of action. Opioids reduce the perception of pain by binding to

opioid receptors, which are found on nerve cells in the brain and periphery (as well as in other organs in the body). The binding of these drugs to opioid receptors in reward regions in the brain produces a sense of well-being, while stimulation of opioid receptors in deeper brain regions results in drowsiness and that can lead to respiratory depression, which can lead to overdose deaths. Presence of opioid receptors in other tissues is responsible for side effects such as constipation and cardiac arrhythmias. The effects of opioids are typically mediated by specific subtypes of opioid receptors (mu, delta, and kappa) that are activated by the body's own (endogenous) opioid chemicals (endorphins, enkephalins). With repeated administration of opioid drugs (prescription or heroin) the production of endogenous opioids decreases, which accounts in part for the discomfort that ensues when the drugs are discontinued (*i.e.*, withdrawal).

People who use opioids non-medically may seek to intensify their experience by taking the drug in ways that deliver the drug more rapidly to their brain. For example, extended-release oxycodone is designed to release slowly and steadily into the bloodstream when taken orally, which minimizes its euphoric effects. People who use pills for their mood elevating effects may crush them to snort or inject the drug, which not only increases the euphoria but also increases the risk for serious medical complications, such as respiratory arrest, coma, and substance use disorder. When people tamper with long-acting or extended-release medicines, which typically contain higher doses because they are intended for release over long periods, the results can be particularly dangerous, as all of the medicine can be released at once. Taking opioids through nasal, smoked, or intravenous routes enhances risks both because of the higher than manufacturer intended dose and the quicker onset.

Another important property of opioid drugs is their tendency, when used repeatedly over time, to induce tolerance. Tolerance occurs when the person no longer responds to the drug as strongly as he or she initially did, thus necessitating a higher dose to achieve the same effect. The establishment of tolerance results from the ability of opioids to desensitize the brain's own natural opioid system, making it less responsive over time.ⁱⁱ This tolerance contributes to the high risk of overdose during a relapse to opioid use after a period of abstinence whether it is intentional, for example when a person tries to quit using or whether it is situational, for example if a user cannot obtain opioid drugs while incarcerated or hospitalized. Users who do not realize they have lost their tolerance during periods of abstinence may initially take the high dosages

that they previously had used before quitting, thus producing overdoses. Another contributing factor to the risk of opioid-related morbidity and mortality is the combined use of benzodiazepines (BZDs) or other central nervous system (CNS) depressants like some sleeping pills, even if these agents are used for the correction indication. Thus, patients with chronic pain who use opioid analgesics along with BZDs are at higher risk for overdose. Similar risks are observed when opioids are combined with alcohol.ⁱⁱⁱ Indeed, the label for these drugs often state, for example, that they should not be used in combination with alcohol and that they should be started at lower doses when used in combination with sedatives. Also, existing and model clinical guidance on opioid prescribing often suggest opioids should not be used with other BZDs.^{iv,v} Unfortunately in many cases practitioners fail to heed practice guidelines and recommendations with respect to co-use.^{vi,vii}

The public-health consequences of opioid misuse are broad and worrisome. For example, use of opioids by pregnant women can result in a withdrawal syndrome in newborns, referred to as neonatal abstinence syndrome, which increased by almost 300 percent in the United States between 2000 and 2009.^{viii} This increase was driven in part by the high rate of opioid prescriptions being given to pregnant women. An estimated 14.4 percent of pregnant women in the United States are prescribed an opioid during their pregnancy.^{ix} Despite producing neonatal abstinence syndrome, methadone has been the acknowledged gold standard for use during pregnancy and there is a growing literature on the use of buprenorphine in pregnant women. These treatments, in combination with behavioral treatment (e.g., MAT), remain highly underused and present the best opportunities to treat opioid use disorder in pregnancy.

Another concern is the transmission of infectious diseases such as HIV and HCV due to injection of heroin or prescription opioids, which has risen along with the increases in individuals injecting opioids. The high prevalence of opioid use also impacts public safety; from 1999-2010, there was a six-fold increase in positive opioid tests among drivers who died within one hour of a crash.^x

Research on National Efforts to Curb the Prescription Opioid Epidemic

Significant efforts have been undertaken across the United States to reduce diversion and misuse of prescription opioids and to reduce opioid overdoses and related deaths. NIDA supports research to understand the impact of these policy changes on rates of opioid misuse, use

disorders, and related public health outcomes. This research has demonstrated the efficacy of multiple types of interventions including:

- Educational initiatives delivered in school and community settings (primary prevention)^{xi}
- Supporting consistent use of prescription drug monitoring programs (PDMPs)^{xii}
- Implementation of overdose education and naloxone distribution programs to issue naloxone directly to opioid users and potential bystanders^{xiii}
- Aggressive law enforcement efforts to address doctor shopping and pill mills^{xiv}
- Diverting individuals with substance use disorders to Drug Courts^{xv}
- Expansion of access to MAT^{xvi}
- Abuse-deterrent formulations for opioid analgesics^{xvii}

In states with the most comprehensive initiatives to reduce opioid overprescribing, the results have been encouraging. Washington State's implementation of evidence-based dosing and best-practice guidelines and enhanced funding for the state's PDMP helped reduce opioid deaths by 27 percent between 2008 and 2012.^{xviii} In Florida, new restrictions were imposed on pain clinics, new policies were implemented requiring more consistent use of the state PDMP, and the Drug Enforcement Administration worked with state law enforcement to conduct widespread raids on pill mills, which resulted in a dramatic decrease in overdose deaths between 2010 and 2012.^{xix} These examples show that state and Federal policies can reduce the availability of prescription opioids and overdose deaths.

Relationship between Prescription Opioids and Heroin Abuse

While the initiatives discussed above are beginning to show successes in the form of decreasing availability of prescription opioid drugs and a decline in overdose deaths in states with the most aggressive policies, since 2010, overdose deaths related to heroin have started to increase (as detailed in the testimony from CDC). There is some concern that the increase in heroin-related overdoses may be an unintended consequence of reducing the availability of prescription opioids. Research has shown that prescription opioid use is a risk factor for heroin use. The incidence of heroin initiation is 19 times higher among those who report prior non-medical pain-reliever use than among those who do not (0.39 percent vs. 0.02 percent).^{xx} However, heroin use is rare in prescription drug users. According to the National Survey on Drug Use and Health, less than four percent of people who had used prescription painkillers non-

medically started using heroin within five years of their initiation of non-medical use of pain medication.^{xviii}

Heroin and prescription opioid pain relievers belong to a single class of drugs—but each are associated with distinct risks. The risk of overdose and negative consequences is even greater with heroin due to the lack of control over the purity of the drug and its possible contamination with other drugs (such as fentanyl, originally a potent prescription opioid but now variants of which are often produced in clandestine labs). All of these factors increase the risk for overdose since users have no way of assessing the potency of the drug before taking it and because in the case of fentanyl contamination, users typically have no opportunity to become tolerant.

There also has been a shift in the demographic of opioid users over the last few decades. In the 1960s, more than 80 percent of people who began using opioids initiated with heroin; in the 2000s, 75 percent of opioid users reported that their first regular opioid was a prescription pain reliever.^{xxii} It also has been reported that current heroin users are more likely to be white, middle-class, and live in more suburban and rural areas; this is consistent with the population of people who report the largest increases in non-medical use of opioid pain relievers over the last decade.^{xxi}

The transition from misusing prescription opioids to using heroin may be part of the natural progression of disease in a subset of users. Evidence from interviews with individuals with heroin use disorder suggest that market forces, including the accessibility, cost, and high potency of heroin are driving increased use of and transition from prescription opioids.^{xxii} Some individuals who have developed dependence on prescription opioids, when faced with the increasing difficulty in obtaining these medications through their providers and the cost of obtaining them illegally, have initiated heroin use, which is cheaper and in some communities easier to obtain than prescription opioids.

In aggregate, these data suggest that preventing the initiation of prescription opioid misuse is a crucial component of efforts to prevent heroin use.

NIDA Efforts to Stem the Tide of Prescription Opioid and Heroin Abuse

NIDA first launched its prescription drug abuse public health initiative in 2001 using evidence-based strategies to (1) enhance our understanding of pain and its management; (2) prevent overdose deaths; and (3) effectively treat opioid use disorders.

Research on Pain and Next Generation Analgesics

Although opioid medications have a legitimate role in the treatment of acute pain and some chronic pain conditions, it is clear that they often are overprescribed or are prescribed without adequate safeguards and monitoring and that their misuse can have devastating effects. This presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. As summarized in a recent report from the NIH Pain Consortium,^{xxiv} there is a pressing need for more research on the effectiveness and safety of using opioids to treat chronic pain as well as on optimal management and risk mitigation strategies. As noted, there are some patients for whom opioids are the best treatment for their chronic pain (e.g., cancer-related pain). However, many other chronic pain patients are inappropriately prescribed opioid medications that may be ineffective or even harmful, often due to lack of adequate clinician education on pain management and screening for substance use disorder risk. This is partially the result of inadequate research on the best approaches to treat various types of pain, but it also is because clinicians may find prescribing opioids to be the easiest and least expensive course for addressing pain. The challenge is to identify the patients for whom opioids are the most appropriate treatment, to identify the best alternative treatments for those who are unlikely to benefit from opioids, and to define the best approach to ensuring that every patient's individual needs are met by a patient-centered health care system.

To better understand these issues, NIDA launched a research initiative on "Prescription Opioid Use and Abuse in the Treatment of Pain." This initiative encourages a multidisciplinary approach using both human and animal studies to examine factors that predispose or protect against opioid abuse and addiction. Funded grants cover clinical neurobiology, genetics, molecular biology, prevention, treatment, and services research. This type of information will help develop screening and diagnostic tools that physicians can use to assess the potential for prescription drug misuse in their patients.

Another important initiative pertains to the development of new approaches to treat pain. NIDA has initiated multiple strategic partnerships to advance development of medications for

pain, leveraging NIDA funds with the strengths and resources of outside organizations, including academic institutions, pharmaceutical and biotechnology companies, private and public foundations, and small businesses. This includes research to identify new pain medicines with reduced abuse, tolerance, and dependence risk, as well as devising alternative delivery systems and formulations for existing drugs that minimize diversion and non-medical use (*e.g.*, by preventing tampering) and reduce the risk of overdose deaths. For example, a partnership with Signature Therapeutics is working to develop an abuse deterrent formulation of oxycodone that uses prodrug technology—attaching an extension to the opioid molecule that renders it inactive if injected, snorted, or smoked; instead it must pass through the digestive system to begin the process of releasing the opioid. Early phase trials have supported safety, dose proportionality, and a clinically beneficial extended release profile.

In addition, new compounds are being developed that exhibit novel properties as a result of their combined activity on two different opioid receptors (*i.e.*, mu and delta). Preclinical studies show that these compounds can induce strong analgesia without producing tolerance or dependence.^{xxv} Researchers are also getting closer to developing a new generation of non-opioid-based medications for severe pain that would circumvent the brain reward pathways, thereby greatly reducing abuse potential. This includes compounds that work through a type of cannabinoid receptor found primarily in the peripheral nervous system.

Education is another critical component of any effort to curb the abuse of prescription medications and must target every segment of society, including healthcare providers (doctors, nurses, dentists, pharmacists). NIDA is advancing addiction awareness, prevention, and treatment in primary care practices through four Centers of Excellence for Physician Information. Intended to serve as national models, these Centers target physicians-in-training, including medical students and resident physicians in primary care specialties (*e.g.* internal medicine, family practice, and pediatrics). NIDA also has developed, in partnership with the Office of National Drug Control Policy, two online continuing medical education courses on safe prescribing for pain and managing patients who abuse prescription opioids. To date, these courses have been completed by over 100,000 clinicians combined.

Developing More Effective Means for Preventing Overdose Deaths

The opioid overdose-reversal drug naloxone can rapidly restore normal respiration to a person who has stopped breathing as a result of overdose from heroin or prescription opioids. Naloxone is widely used by emergency medical personnel and some first responders. Beyond first responders, some communities have established overdose education and naloxone distribution programs that issue naloxone directly to opioid users and their friends or loved ones, or other potential bystanders, along with brief training in how to use these emergency kits. Such programs have been shown to be effective, as well as cost-effective, ways of saving lives. CDC reported that, as of 2010, lay-distributed naloxone had resulted in more than 10,000 overdose reversals nationwide since 1996.^{xxvi}

For many years, naloxone was available only in an injectable formulation that was generally carried only by medical emergency personnel. However, FDA recently approved a new hand-held auto-injector of naloxone to reverse opioid overdose that is specifically designed to be given by family members or caregivers. NIDA and other agencies are working with the FDA and drug manufacturers to support the development and approval of a user-friendly intranasal formulation that would match the pharmacokinetics (*i.e.*, how much and how rapidly the drug gets into the body) of the injectable version. More market competition is expected to help bring down the cost of naloxone products.

Research on the Treatment of Opioid Addiction

There are a number of medications available for the treatment of opioid use disorders, both for patients in acute withdrawal and to support long term recovery. Medications have become an essential component of an ongoing treatment plan, enabling opioid-addicted persons to regain control of their health and their lives. Agonist medications developed to treat opioid addiction work through opioid receptors but are safer and less likely to produce the harmful behaviors that characterize addiction, because the rate at which they enter and leave the brain is slower. The three classes that have been developed to date include (1) agonists, *e.g.* methadone (Dolophine or Methadose), which activate opioid receptors; (2) partial agonists, *e.g.* buprenorphine (Subutex, Suboxone, Zubsolve), which also activate opioid receptors but produce a diminished response; and (3) antagonists, *e.g.* naltrexone (Vivitrol), which block the receptor and interfere with the rewarding effects of opioids. Physicians can select from these options on the basis of a patient's specific medical needs. The evidence strongly demonstrates that

methadone, buprenorphine, and injectable naltrexone (e.g., Vivitrol), when administered in the context of an addiction treatment program, all effectively help maintain abstinence from other opioids, reduce opioid use disorder-related symptoms, and reduce the risk of infectious disease and crime.^{xxvii} Two comprehensive Cochrane reviews, one analyzing data from 11 randomized clinical trials that compared the effectiveness of methadone to placebo and another analyzing data from 31 trials comparing buprenorphine or methadone treatment to placebo,^{xxviii,xxix} found that:

- Patients on methadone were over four times more likely to stay in treatment and had 33 percent fewer opioid-positive drug tests compared to patients treated with placebo;
- Methadone treatment significantly improves treatment outcomes alone and when added to counseling; long-term (beyond six months) outcomes are better for patients receiving methadone, regardless of counseling received;
- Buprenorphine treatment significantly decreased the number of opioid-positive drug tests, multiple studies found a 75-80 percent reduction in the number of patients testing positive for opioid use;
- Methadone and buprenorphine are equally effective at reducing opioid use; no differences were found in opioid-positive drug tests or self-reported heroin use when treating with these medications.

To be clear, the evidence supports long term maintenance with these medicines in the context of behavioral treatment and recovery support, not short term detoxification programs aimed at abstinence.^{xxx} Abstinence from all medicines may be a particular patient's goal and that goal should be discussed between patients and providers. However the scientific evidence suggests the relapse rates are high when tapering off of these medications and treatment programs with an abstinence focus generally do not facilitate patients' long term, stable recovery. It is often the case that patients with good long-term outcomes are the ones who engaged in MAT although cycling in and out of treatment is not unusual in the path to a stable recovery.^{xxxii, xxxiii} Maintenance treatments have also been shown to be protective against injecting and overdose.^{xxxii, xxxiii}

Ongoing NIDA research is working to develop improved strategies for the implementation of these evidence-based interventions. This includes research to better

understand the role environment—be it social, familial, structural, or geographic—plays in preventing opioid use and in the success of prevention and treatment interventions; and how to tailor prevention and treatment interventions to individuals with unique needs, including those in the criminal justice system or with HIV.

Conclusion

NIDA will continue its close collaborations with other Federal Agencies and community partners with a strong interest in preserving public health to address the ongoing challenge posed by abuse of prescription and non-prescription opioids in this country. We commend the Subcommittee for recognizing the serious and growing challenge associated with this exceedingly complex issue. Indeed, prescription opioids, like other prescribed medications, do present health risks but they are also powerful clinical tools for the treatment of pain. It is imperative that we strive to achieve a balanced approach to ensure that people suffering from pain can get the relief they need while minimizing the potential for negative consequences. We support the development and implementation of multipronged, evidence-based strategies that minimize the intrinsic risks of opioid medications and make effective, long term treatments more widely available.

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Mr. MURPHY. Thank you.
Dr. Throckmorton, 5 minutes.

STATEMENT OF DOUGLAS C. THROCKMORTON

Dr. THROCKMORTON. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs within FDA's Center for Drug Evaluation and Research. Thank you for the opportunity to be here today to discuss FDA's role in combating opioid abuse and encouraging the safe use of these important drugs.

Our goal is to find the balance between needing to treat patients with pain, including the use of opioids where appropriate, and needing to reduce opioid drug abuse. This work is being done together with other parts of the Federal Government, and we know that a successful and sustainable response must include Federal and State Government, public health officials, opioid prescribers, addiction experts, researchers, manufacturers, and patient organizations.

For our part, FDA plays a central role in the regulation and use of drugs from their discovery and throughout their marketing. For example, when FDA reviews a drug for possible marketing, we also approve drug labeling, which includes information about approved uses about the medicine, as well as information about potential safety risks. FDA also carefully follows drugs after they are marketed, including opioid drugs. Where necessary, this enables us to take a variety of actions to improve their safe use, such as changes to approved labeling.

The first area of FDA activity I'd like to highlight is our work to support the development of abuse-deterrent formulations that make opioids harder or less rewarding to abuse. While this is not a silver bullet that will prevent all abuse, FDA believes abuse-deterrent opioids can help reduce opioid abuse. To incentivize their development, FDA recently issued final guidance on abuse-deterrent formulations, guidance we are using now to meet with sponsors interested in developing them.

To date, FDA has received some 30 investigational new drug applications from manufacturers. In addition, we have approved four opioid drugs with abuse-deterrent claims in their labeling.

Overall, then, while we are in the early stages of development, I am encouraged by this level of work. FDA envisions a day not far in the future when the majority of opioids in the marketplace are in effective, abuse-deterrent forms.

Next, with regards to prescribing opioids, we know that they are powerful medicines, and FDA believes that it is critically important to ensure that prescribers have high quality education about how to use them in pain management.

Over the past several years, FDA has done several things to improve educational materials on opioids. For example, we recently finalized required changes to the approved labels of extended-release, long-acting opioids, changing their indication to inform prescribers that these drugs should only be used for pain severe enough to require daily around-the-clock treatment when alternative treatments would not work.

At the same time, FDA strengthened significantly the safety warnings on these opioids. We want prescribers to use them with care, and today, the labels for extended-release, long-acting opioids are among the most restrictive of any drugs that we have in the center, and have clear language that calls attention to their potentially life-threatening risks.

FDA's also working to improve the information available for prescribers in other ways. Under certain circumstances, FDA can require manufacturers, as a part of a risk evaluation and mitigation strategy, to address safety concerns such as opioid abuse. In 2012, FDA required manufacturers to fund the development of unbiased continuing education programs on opioid prescribing practices for prescribers. In the first year since that program has been in place, approximately 6 percent of the 320,000 prescribers, around 20,000 prescribers of extended-release and long-acting opioids, have completed one of those courses. We believe this training for prescribers is important. We also support mandatory education for prescribers of opioids, as called for by the administration in the 2011 Prescription Drug Abuse Prevention Plan, and reemphasized in the 2014 National Drug Control Strategy.

Finally, FDA has been working with many other stakeholders, including the agencies here today, to explore the best ways to prevent overdose deaths by the expanded use of naloxone. As others have said, it can and does save lives. FDA is working to facilitate the development of naloxone formulations that could be easier to use by anyone responding to an overdose. First, FDA meets with manufacturers whenever needed and is using whatever tools we can to expedite product development. We recently approved the first auto-injector formulation of naloxone, which is intended to be administered by people witnessing an overdose, such as family members and caregivers. We completed that review and approved this product in 15 weeks.

Going forward, we continue to work on how best to use naloxone. As a part of this work, FDA, and many of the others agencies at this table, are planning a public meeting in July to bring together key stakeholders to deal with questions of access, coprescribing of naloxone, and State and local best practices.

In conclusion, as a society, we face an ongoing challenge and a dual responsibility. We must balance efforts to address opioid drug misuse, abuse, and addiction against the need for access to appropriate pain management. These are not simple issues and there are no easy answers. FDA is taking important actions we hope will achieve this balance. We welcome the opportunity to work with Congress, our Federal partners, the medical community, advocacy organizations, and the multitude of interested communities and families to turn the tide on this devastating epidemic.

Thank you for this opportunity to testify. I look forward to answering any questions that I can.

[The prepared statement of Dr. Throckmorton follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT
OF
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FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

MAY 1, 2015

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs, within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important role that FDA plays in combating opioid abuse and encouraging the safe use of these drugs by patients, as part of FDA's mission to protect and promote the public health by ensuring the safety, efficacy, and quality of medical products.

Opioid analgesics (e.g., hydrocodone, oxycodone, morphine, and fentanyl) play a vital role in the treatment of pain and the availability of multiple effective pain medicines, including opioids, for patients with pain is an important component of proper pain management. Because individual patients respond differently to pain medications, having a variety of pain drugs available is important to meet the needs of patients. Unfortunately, in addition to this important role in the management of pain, the abuse and misuse of opioid medications has become a public health crisis. Recognizing this, combating opioid misuse, abuse, addiction, and overdose is a priority for the Agency, and FDA has taken many steps to address this problem. As a science-based Agency, our work is guided by all of the available information, including basic science, clinical trials, and studies looking at the epidemiology of opioid use and abuse. In my remarks, I'd like to discuss just a few of the important FDA activities we believe are making a difference in this

crisis; activities we believe will help ensure the continued availability of these important medications for patients who genuinely need them, while also reducing the risks of their abuse and misuse. I will do this by discussing these examples within a context of the larger role FDA plays in regulating medicines in the United States.

I would like to note at the outset, however, that while FDA plays an important role, we cannot fix the opioid misuse and abuse epidemic alone. A successful and sustainable response will require the action of many stakeholders. This hearing helps to highlight the broad range of work going on in many parts of the Federal government aimed at reducing opioid abuse and improving the safe use of opioid medicines, and you will hear today from our other Federal partners about the various complementary efforts they are undertaking to address this complex issue. To succeed, this comprehensive approach must include Federal and state governments, public health, opioid prescribers, addiction experts, researchers, industry, patient organizations, and others. Working together, we can and must address opioid abuse and misuse now.

FDA's Role

When FDA reviews a drug product application to determine whether the drug is safe and effective, we also approve labeling that describes approved uses for the medicine, potential safety risks, and other information to support safe use of the medicine—information that health care providers can then use to make the decision about what is best for their patients.

As with other drugs, the Agency carefully reviews the evidence to determine whether a new opioid product's expected benefits outweigh its potential risks. In addition, we also consider the risk that could occur if opioid drugs are misused or abused.

FDA also carefully follows opioid medicines after they are on the market so that we can understand how they are being used in clinical practice and measure their impact on the public health. Where necessary, this enables us to make changes to the labeling of these drugs to improve their safe use.

Next, I'd like to discuss a few of the initiatives FDA is taking to facilitate the development of safer pain medicines, as well as actions we have taken to support the appropriate use of opioid analgesics.

Abuse-deterrent Formulations of Opioids

One area of great promise to reduce the abuse of opioids is to develop formulations that are specifically designed to deter abuse. Abuse-deterrent formulations target known or expected routes of abuse, such as crushing the product or extracting the active ingredient from the product to facilitate rapid release of the opioid following swallowing, snorting, or injection, with a goal of reducing the abuse of the product.

While not a silver bullet that will prevent all abuse, FDA sees the development of these abuse-deterrent opioids as an important step toward balancing appropriate access to opioids for patients with pain with the critical need to reduce opioid misuse and abuse.

Given the importance of this balance, the essential features of successful abuse-deterrent formulations are: (1) the product must deliver a consistent and effective dose of opioid when used as intended for pain management, and (2) based on the science, the product's potentially abuse-deterrent properties can be expected to, or actually do, result in a significant reduction in that product's abuse potential. In addition, the labeling that describes the abuse-deterrent features of the product must be based on scientific data, and any labeling based on premarket studies must be confirmed using post-market data to assess abuse deterrence in everyday clinical practice.

To incentivize the development and broad use of these new opioid drug products with abuse-deterrent features, FDA first created a draft guidance in 2013 that lays out a roadmap for developers to follow. Since then, we have carefully reviewed comments from scientists, academics, and manufacturers to refine and improve that draft. On April 1, 2015, FDA issued the final guidance on abuse-deterrent formulations of opioids. In addition to laying out the pathway for drug makers to follow in developing these products, it sets forth how we intend to review data submitted regarding the products' potentially abuse-deterrent properties and how we will evaluate proposed labeling describing those properties.

In addition, we are actively meeting with manufacturers about developing these products and to date, we have approved four opioid formulations with abuse-deterrent claims in their labeling. Importantly, the sponsors of these products—and the sponsor of any future products so labeled—are required to study the impact of their products' abuse-deterrent properties on actual abuse in the community, and FDA will revisit the labeling of these products as necessary, based in part on the results of these studies. We hope this labeling will encourage practitioners to integrate these products into their practices.

With FDA's focus on abuse-deterrent opioid products, including the labeling guidance and last October's public meeting, which discussed a range of regulatory issues related to these products, interest in producing these products has increased dramatically: FDA has already received some 30 investigational new drug (IND) applications from manufacturers seeking to conduct clinical trials on potential abuse-deterrent products. Many of these manufacturers are exploring promising alternatives to the currently marketed abuse-deterrent formulations, which are primarily designed to resist crushing and extraction. The INDs that we have received present a fascinating array of scientific techniques and approaches to abuse-deterrent formulation. And it helps FDA envision a day, not so far in the future, when the majority of opioids in the marketplace are in effective, abuse-deterrent forms; forms that substantially reduce all forms of abuse, including abuse by the oral, intranasal, and intravenous routes.

Labeling Changes for Opioids

The second activity I would like to discuss relates to work FDA is doing to improve the information available to prescribers about how best to use opioid medications and to help prescribers determine if an opioid is the right choice for their patient. The primary tool that FDA uses to inform prescribers about the approved uses of medications is the product labeling. The approved information, which includes scientific and clinical information gathered about the drug, including clinical pharmacology studies, animal studies, clinical studies, and post-market experience, is used by prescribers to make the decisions about what is best for their patients.

As mentioned before, FDA continuously monitors the use of drugs in the marketplace. Using what we have learned, over the past several years, FDA has made significant changes to opioid product labeling in an effort to improve their safe use and to reduce their misuse and abuse. For example, based on our analysis of the serious risks of abuse, addiction, overdose, and death associated with the currently marketed extended-release, long-acting (ER/LA) opioids, we determined that changes needed to be made to their labeling to help provide additional information to prescribers.

Last year we changed the indication for these products to inform practitioners that these drugs should only be used for pain severe enough to require daily, around-the-clock treatment, when alternative treatment options, including non-opioid analgesics, were ineffective, not tolerated, or would be otherwise inadequate to provide sufficient pain relief.

FDA has also significantly augmented the safety warnings for these opioids, and today the labels for ER/LA opioid medicines have some of the most restrictive language that can be found in drug labeling, including a boxed warning about their potential for abuse and clear language that calls attention to potential serious or life-threatening risks of opioids, including the risk of fatal overdose. We also added a warning that maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require careful management, according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother's womb. With these changes, FDA is working to support the safest possible uses of these powerful medicines in appropriately selected and monitored patients.

Prescriber and Patient Education

FDA also is working in other ways to improve the information available to prescribers of opioid medications. It is critically important to ensure that prescribers have adequate, high-quality education in appropriate pain management, including the use of opioids. It is also important that prescribers know the content of the most current drug labels to help them determine whether these products are appropriate for their patients and to help them educate their patients about the appropriate use of opioids, their potential risks, and proper storage and disposal techniques.

Under appropriate circumstances, FDA can require manufacturers to develop risk evaluation and mitigation strategies (REMS) to ensure that the benefits of a drug outweigh the risks. In July 2012, after an extensive review, FDA approved a REMS for manufacturers of ER/LA opioids.

This REMS acknowledges the critical role that our nation's front-line health care professionals play in efforts to reduce the abuse and misuse of opioids. To assist prescribers, as an important element of this REMS, manufacturers are required to fund the development of continuing education programs on proper opioid-prescribing practices for prescribers. These programs are provided by accredited continuing education providers, using a syllabus developed by FDA, with input from many stakeholders, and are audited to ensure the content is accurate and unbiased. Using these voluntary prescriber training programs will assist prescribers in their efforts to treat appropriately selected patients with opioids and minimize the risks of abuse and misuse.

The first of these voluntary prescriber training programs was rolled out on March 1, 2013. Although this training is an important public health measure, FDA continues to support mandatory education for prescribers, as called for by the Administration in the 2011 Prescription Drug Abuse Prevention Plan, and re-emphasized in the 2014 National Drug Control Strategy.

FDA also recognizes the importance of providing educational materials for patients. In addition to training for prescribers, patients also need access to educational materials to help guide the use of opioid medicines. Under the REMS for ER/LA opioids, manufacturers have developed a

patient-friendly counseling tool for prescribers to give to every patient, when they write a prescription for an ER/LA opioid. The REMS also includes a product-specific Medication Guide to be provided to the patient when they pick up their prescriptions. Included in these materials is information on how to safely store medications, while still in use, and what to do with the leftover supply, when it is no longer needed. These educational programs for both providers and patients are an important part of the comprehensive approach to reducing opioid misuse and abuse. In addition, these programs serve as a part of the Secretary's Opioid Initiative, which focuses on improving prescribing practices, expanding the use of naloxone to reverse opioid overdose, and enhancing access to medication-assisted treatment for opioid use disorders.

Rescheduling of Hydrocodone Combination Products

FDA also plays a role in limiting inappropriate access to opioids, as demonstrated by our role in recommending additional restrictions on the use of hydrocodone-containing, fixed-combination drugs. For the hydrocodone combination products, after our analysis, HHS recommended that the Drug Enforcement Administration (DEA) move these products from Schedule III to the more restrictive Schedule II. We based our recommendation on factors including the products' actual or relative potential for abuse, their liability to cause dependence, and dangers they might pose to public health. Rescheduling took effect in October of last year.

Increasing Access to Naloxone

Finally, FDA understands the critical importance of preventing overdose deaths—the most devastating consequence of this public health crisis. We have been working with many other stakeholders to explore the best ways to treat overdoses of opioids, including overdoses of FDA-approved opioid medications. Naloxone is an injectable medication that is the standard treatment to rapidly reverse the overdose of either prescription (e.g., oxycodone) or illicit (e.g., heroin) opioids. Naloxone's ability to reverse opioid overdose has long been recognized. But for many years, the available products were primarily used by medical personnel and not always well-suited for use by others. That is why FDA, in collaboration with other agencies across the Federal government, has sought to facilitate the development of naloxone formulations that would be easier to use by anyone responding to an opioid overdose in the community.

To make progress on this goal, we used our expedited review programs, including fast-track designation and priority review, to approve the first auto-injector formulation of naloxone, which is intended to be administered by patients and their families and caregivers. An auto-injector has the advantage of being easier and quicker to use in an emergency situation than vial and/or syringe formulations that are currently approved. As an example of the priority that the Agency places on our role in helping address the abuse and overdose crisis, we completed our review and approved this product in just 15 weeks so that auto-injectors could be made available as quickly as possible.

Recognizing the pressing need for additional formulations and routes of delivery of naloxone, we continue to use our expedited review programs to speed the progress of new formulations of naloxone. Having an approved product is a major step forward, but it's also crucial to get it into the hands of people so they can use it when and where it's needed. That's why FDA, in partnership with other HHS agencies, is planning a public meeting in July to bring together key stakeholders to deal with questions of access, co-prescribing of naloxone along with opioids, and state and local best practices.

CONCLUSION

In summary, we face an ongoing challenge and a dual responsibility—we must balance efforts to address misuse, abuse, and addiction that harm our families and communities against the need for access to appropriate pain management. There can be no doubt that there is much to be done—and we must act now. In my testimony I have discussed some of the many activities that FDA is working on in this area. These are not simple issues and there are no easy answers. Given the complexity of this issue, real and enduring progress will require a multi-faceted approach combined with the dedication, persistence, and full engagement of all parties. We welcome the opportunity to work with Congress, our Federal partners, the medical community, advocacy organizations, and the multitude of interested communities and families to turn the tide on this devastating epidemic.

Thank you for your continued interest in this important topic and for the opportunity to testify regarding FDA's contributions to progress on this issue. I am happy to answer any questions you may have.

Mr. MURPHY. Thank you, Doctor.
Dr. Houry.

STATEMENT OF DEBRA HOURY

Dr. HOURY. Chairman Murphy, Ranking Member DeGette, I would like to thank you for inviting me here today to discuss this very important issue. I would also like to thank the committee for your continued interest in prescription opioid abuse and overdose. My name is Dr. Debra Houry, and I am the director of the National Center for Injury Prevention and Control at the CDC.

As a trained emergency room physician, I have seen firsthand the devastating impact of opioid addiction on individuals and their families, as well as the importance of prevention. Together, we have witnessed a deadly epidemic unfolding in States and communities across the country. The overdose epidemic is driven, in large part, by fundamental changes in the way healthcare providers prescribe opioid pain relievers. Enough prescriptions were filled in 2012 for every American adult to have their own bottle of pills. As the amount of opioids prescribed increased, so has the number of deaths.

In alignment with the Department's initiative, I want to highlight CDC's work in developing evidence-informed opioid prescribing guidelines for chronic pain and providing direct support to States to implement multi-sector prevention programs.

CDC is currently developing guidelines for the prescribing of opioids for chronic noncancer pain. This undertaking is responsive to a critical need in the field. These new guidelines will redefine best practices around opioid prescribing for chronic pain and make important advances in protecting patients. The audience for these guidelines are primary care practitioners, who account for the greatest number of prescriptions for opioids compared to other specialties. The guidelines process is underway, and our goal is to share a draft for public comment by the end of this year. We have plans in place to encourage uptake and usage of the guidelines among providers, which is key for improving prescribing practices.

The second activity I would like to highlight is our major investment in State-level prevention. States are at the front lines of this public health issue, and CDC is committed to equipping them with the expertise they need to reverse the epidemic and protect their communities. Utilizing the newly appropriated \$20 million, we recently published a new funding opportunity called Prescription Drug Overdose: Prevention for States. It builds upon existing CDC-funded State programs and targets States that have a high drug overdose burden and those that demonstrate readiness needed to combat the epidemic. It requires collaboration across sectors for a truly comprehensive response.

The goals for this program are to make prescription drug monitoring programs more timely, easier to use, and able to communicate with other State PDMPs, to implement Medicaid or Workers' Compensation interventions to protect patients at risk, and to bring data-driven prevention to the communities struggling with the highest rates of drug abuse and overdose. States also will be given the flexibility to use the program to respond to emerging cri-

ses and develop innovative interventions so they know what works to reduce overdose and save lives in their community.

The development of opioid prescribing guidelines and our State prevention program are two key ways that CDC's broad work on the epidemic contributes to the Department's initiative.

We are also examining the increase in heroin use and overdose. Heroin overdose deaths have more than doubled since 2010, and prescription opioid abuse, a key risk factor for heroin use, has contributed significantly to this rise in heroin use and overdose. We will leverage our scientific expertise to improve public health surveillance of heroin and evaluate effective strategies to prevent future heroin overdoses.

Addressing this complex problem requires a multifaceted approach and collaboration among a variety of stakeholders, but it can be accomplished, particularly with the ongoing efforts of all of the organizations represented here on this panel.

CDC is committed to tracking and understanding the epidemic, supporting States working on the front lines of this crisis, and providing healthcare providers with the data, tools, and guidance they need to ensure safe patient care.

Thank you again for the opportunity to be here with you today and for your continued work and support of us protecting the public's health. I look forward to your questions.

[The prepared statement of Dr. Houry follows:]

Testimony of Dr. Debra Houry, Centers for Disease Control and Prevention (CDC)

for the

Subcommittee on Oversight and Investigations

House Energy and Commerce Committee

Hearing on Opioid Abuse

May 1, 2015

Chairman Murphy, Ranking Member DeGette, I would like to thank you for inviting me here today to discuss this very important issue. I'd like to also thank the committee for your continued interest in the prevention of opioid abuse and overdose. My name is Dr. Debra Houry and I am the Director of the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC). The activities related to the prevention of prescription drug overdose at the agency are under my leadership. As a trained emergency room physician, I have seen firsthand the devastating impact of opioid addiction on individuals and their families. Other centers at CDC are also working to address the many health impacts of this unprecedented epidemic. As I testify today, CDC staff are in southern Indiana to help stem a large HIV outbreak caused by injection drug use of prescription opioids. The outbreak is only the most recent manifestation of a deadly epidemic unfolding in states and communities across the country.

Deaths from drug overdoses have been rising steadily over the past two decades and have become the leading cause of injury death in the United States¹. This growth in drug overdose deaths consists in large part of a quadrupling in the number of deaths involving prescription opioid pain relievers. As the nation's health protection agency, CDC has applied public health

¹ Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. 2014. Retrieved from: <http://www.cdc.gov/injury/wisqars/fatal.html>

principles to identify the connection between inappropriate opioid prescribing and overdose deaths. The prescription drug overdose epidemic is driven in large part by fundamental changes in the way healthcare providers prescribe opioid pain relievers: 259 million prescriptions were written for opioids in 2012², enough for every American adult to have his or her own bottle of pills. As the amount of opioids prescribed has increased, so has the number of overdose deaths.

CDC is working to reverse the prescription drug overdose epidemic by focusing on three areas that are central to CDC's mission and complement the work of our sister agencies who join me here today. The first is to protect the public's health by tracking overdose and prescribing trends and by improving the quality of the data collected. These data can be used to identify those at highest risk and to target interventions. The second is to strengthen state efforts by helping states to scale up effective strategies to combat the epidemic. The third is to supply healthcare providers with the data, tools, and guidance needed to improve patient safety, including through appropriate prescribing of opioids. This approach leverages CDC's unique scientific and programmatic expertise. Our activities are conducted in coordination with other Federal agencies and departments, are aligned with the Department's initiative to address opioid-drug related overdose, death, and dependence, and would be expanded by the critical investments in combating opioid abuse and overdose that the President included in his Fiscal Year 2016 Budget.

This initiative focuses on three broader priority areas—improving opioid prescribing practices, expanding use of naloxone, and increasing access to medication-assisted treatment. I want to highlight CDC's central role in the first of these priority areas by focusing on two

² Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012, *Morbidity and Mortality Weekly Report*. July 4, 2014, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w

activities at CDC that are key pieces of this initiative—developing evidence-informed opioid prescribing guidelines for chronic pain and providing direct support to states to implement robust, multi-sector prevention programs.

CDC's Opioid Prescribing Guidelines for Chronic Pain

CDC is developing guidelines for the prescribing of opioids for chronic pain outside of the end-of-life care setting. This undertaking is responsive to a critical need in the field. There is a lack of high-quality guidelines on opioid prescribing³. And among those that do exist, many have key limitations, in that they may be outdated and fail to account for the most recent evidence about risks related to dosage or technological advances (such as the enhancement of prescription drug monitoring programs).

CDC's guidelines will include input from national experts, be responsive to the most recent scientific evidence, and will proceed through a development process carefully tailored to minimize any risk of conflicts of interest. These new guidelines will articulate best practices around opioid prescribing for chronic pain and make important advances in protecting patients. The audience for these guidelines is primary care practitioners, who account for the greatest number of opioid prescriptions compared to other specialties. Primary evidence informing the guideline development comes from the Agency for Healthcare Research and Quality's 2014 systematic review on *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*⁴. This review rigorously addressed the effectiveness of long-term opioid therapy for

³ Nuckols, Teryl K., et al. "Opioid prescribing: a systematic review and critical appraisal of guidelines for chronic pain." *Annals of internal medicine* 160.1 (2014): 38-47.

⁴ Chou R, Deyo R, Devine B, Hansen R, Sullivan S, Jarvik JG, Blazina I, Dana T, Bougatsos C, Turner J. The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain. Evidence Report/Technology Assessment No. 218. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 14-E005-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2014. www.effectivehealthcare.ahrq.gov/reports/final.cfm

outcomes related to pain, function, and quality of life and the harms and adverse events associated with opioids.

The process of developing these guidelines is comprehensive and CDC is working diligently to publish the guidelines next year. Informing the process is an expert panel comprised of individuals carefully vetted as subject matter experts, representatives of key primary care specialties, and representatives of state agencies that have developed opioid prescribing guidelines with broad stakeholder input. Our federal partners, many of whom join me on the panel here today, will also be engaged and will be able to provide input on the process. Our goal is to share draft guidelines for public comment by the end of this year.

While release of the guidelines will be an important contribution, of equal importance is the need to widely disseminate and encourage uptake and usage of the guidelines among providers. In addition to development of the guidelines themselves, CDC also is planning activities to promote wide dissemination and to encourage use among providers following their release. CDC is developing a plan to leverage existing partnerships, federal and otherwise, to promote uptake of the guidelines.

CDC's Direct Support to States to Prevent Prescription Drug Overdose

The second key activity I want to highlight today is our major investment in state-level prevention.

States are at the front lines of this epidemic and CDC is committed to equipping them with the resources and expertise they need to reverse the epidemic and protect their residents, families, and communities. The most impactful state-level approaches to date have tackled the epidemic on multiple fronts—promoting effective Prescription Drug Monitoring Programs, or

PDMPs; leveraging the states' role as a healthcare payer to improve patient safety; and engaging hard-hit communities to focus efforts where the epidemic is the most severe. At CDC, we have seen the effectiveness of this multi-front, multi-sector approach and made it the foundation of our state prevention programs.

In March, we published a new funding opportunity called *Prescription Drug Overdose: Prevention for States*. This program is funded through the \$20 million newly appropriated to CDC in FY 2015 and builds upon existing CDC-funded state programs that address the epidemic. The new *Prevention for States* program targets states that have a high drug overdose burden and that demonstrate readiness needed to respond to the epidemic. It requires collaboration across sectors, including public health, law enforcement, and substance abuse services agencies, for a truly comprehensive response. Funded states will advance prevention on multiple fronts—including making PDMPs more timely, easier to use, and able to communicate with the PDMPs of other states; implementing interventions that can be integrated within state Medicaid or Worker's Compensation programs to protect patients at risk; and bringing data-driven prevention to the communities struggling with the highest rates of drug abuse and overdose. Critically, states also will be given the flexibility to use the program to respond to emerging crises and evaluate existing interventions so they know what works best to reduce overdoses and save lives.

This year, CDC will fund approximately 16 states with awards of up to a million dollars per year over the next four years. The President's FY 2016 Budget proposes a major expansion of this program. The proposed \$48 million increase for the new *Prevention for States* program would ensure CDC's state-level investment in prevention can reach all 50 states and Washington, D.C. for a truly national response to the epidemic. This funding will also help CDC better

understand the role and impact of naloxone in preventing overdose deaths. Of the proposed \$48 million increase for FY 2016, \$3 million is allocated to apply CDC’s evaluation expertise to assess the impact of a major SAMHSA naloxone initiative to promote more widespread use of this life-saving drug. We will also continue to support SAMHSA’s leading role in advancing access to medication-assisted treatment, for instance, by analyzing gaps between demand for opioid abuse treatment and treatment availability.

In addition to the work we are doing on the prescription drug overdose epidemic, we are examining the increase in heroin use and overdose. Heroin overdose deaths have more than doubled since 2010⁵ and prescription opioid abuse, a key risk factor for heroin use, has contributed significantly to this rise in heroin use and overdose. People who use prescription opioids non-medically—that is, without a prescription or for the feeling the drug causes—are at an increased risk for heroin use. Among new heroin users, approximately three out of four report having abused prescription opioids prior to using heroin.⁶ In addition, data show that people reporting past-year nonmedical use of opioids were 19 times more likely to initiate heroin use than people who did not report past-year nonmedical use of opioids.⁷ There were an estimated 11 million people who used prescription opioids non-medically in 2011⁸. While most people who

⁵ Increases in Heroin Overdose Deaths – 28 states, 2010 to 2012, *Morbidity and Mortality Weekly Report*, October 3, 2014, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6339al.htm>; See also Hedegaard, H, Chen, L, Warner, M, Drug-poisoning deaths involving heroin: United States, 2010-2013, National Center for Health Statistics, NCHS Data Brief, Number 190, March 2015, <http://www.cdc.gov/nchs/data/databriefs/db190.htm>

⁶ Cicero TJ, Ellis MS, Surrau HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821–6.

⁷ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. <http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

⁸ Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012

use prescription opioids nonmedically do not go on to use heroin, the small percentage (about four percent) who do account for a majority of people recently initiating heroin use.⁹

More research is needed to better understand the characteristics of people who use heroin after abusing prescription opioids. CDC will continue our work in addressing heroin overdoses by leveraging our scientific expertise to improve public health surveillance of heroin and evaluate effective strategies to prevent future heroin overdoses. For instance, under our new *Prevention for States* program, states may use funds to evaluate the impact of state policies on heroin overdose rates and track heroin outcomes in their state. In addition, as part of the President's FY 2016 Budget, \$6 million would be used to collect near real-time emergency department data as well to explore the most economic and efficient way to collect heroin overdose data. The FY 2016 Budget request also includes an increase of \$5.0 million for Health Statistics to expand electronic death reporting to provide faster, better quality data on deaths of public health importance, including Prescription Drug Overdose deaths. These efforts to improve the timeliness of jurisdiction reporting and to modernize the national vital statistics infrastructure are contributing to developing a system capable of supporting near real-time surveillance.

In conclusion, prescription drug abuse and overdose is a serious public health issue in the United States. The burden of prescription drug abuse and overdose affects not only individuals and families, but also communities, employers, the healthcare system, and public and private insurers. Addressing this complex problem requires a multi-faceted approach and collaboration between public health, clinical medicine, and public safety at the Federal, state, and

⁹ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013.
<http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>

local levels. But, it can be accomplished—particularly with the ongoing efforts of all of the entities represented here on this panel and the new investments proposed in the President’s Budget. CDC is committed to tracking and understanding the epidemic, supporting states working on the front lines of this crisis, and providing healthcare providers with the data, tools, and guidance they need to ensure safe patient care.

Thank you again for the opportunity to be here with you today and for your continued support of our work in protecting the public’s health. I look forward to your questions.

Mr. MURPHY. Thank you, Doctor.
Pamela Hyde, welcome back.

STATEMENT OF PAMELA S. HYDE

Ms. HYDE. Good morning, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee. Thank you for inviting SAMHSA to be part of this hearing, and thank you for your interest in this important public health issue.

According to SAMHSA's National Survey on Drug Use and Health, the prevalence rate of nonmedical use of prescription opioids is high, approximately 4.5 million individuals in 2013. Heroin use is much lower, About 289,000 individuals reporting past month use, but that's doubled in 5 years.

Fortunately, the nonmedical use of pain relievers has actually decreased some from 2009 to 2013, especially among young people 12 to 17. However, as you know, overdoses and overdose-related deaths from both prescription drugs and heroin have risen dramatically among all ages. And as you've heard, few who need treatment are receiving the comprehensive community-based services they need to live lives in recovery, free of addiction.

SAMHSA believes prevention is the priority and recovery is the goal. SAMHSA's programs, data, practice improvement, public education, and regulatory efforts are all designed to prevent addiction and overdoses, help provide the treatment and services needed for people with substance abuse disorders to achieve recovery, support their families, and foster supportive communities.

SAMHSA funds the American Academy of Addiction Psychiatry, together with six other medical societies, to train prescribers in the best approaches to pain management. SAMHSA also educates physicians on medication-assisted treatment for opioid addiction. SAMHSA's Addiction Technology Transfer Centers provide training and materials on opioid use disorders, and are cofunded with NIDA to distribute research-based best practices to the field of addiction treatment.

To help prevent opioid-overdose-related deaths, SAMHSA alerted States last year that substance abuse treatment block grant funds may be used to purchase and distribute naloxone and increase education and training on its use. Also in 2014, SAMHSA updated its opioid overdose prevention toolkit to educate individuals, families, first responders, and others about steps to prevent and reverse the effects of opioid overdoses, including the use of naloxone. This toolkit's one of the most downloaded resources on SAMHSA's Web site.

The President's 2016 budget includes \$12 million in discretionary grants for States to purchase and distribute naloxone, equip first responders in high risk communities, and support education on the use of naloxone and other overdose prevention strategies.

SAMHSA also supports medication-assisted treatment as part of a recovery-oriented, person-centered care model. Medication-assisted treatment is not meant as a standalone approach, but rather is designed to include medication, counseling, behavioral therapies, and recovery supports.

In March 2015, SAMHSA issued revised Federal guidelines for opioid treatment programs which highlight this recovery-oriented care model, and encouraged the use of any of the three FDA-ap-

proved medications for the treatment of opioid use disorder based on an assessment of each individual's unique needs.

SAMHSA's also taking an integrated clinical care approach as part of a new 2015 grant program to expand and enhance the availability of medication-assisted treatment and other clinically appropriate services in States with the highest rates of opioid admissions. The President's 2016 budget proposes to double this program.

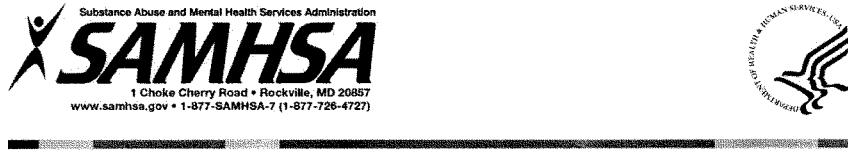
In collaboration with DOJ and ONDCP, SAMHSA added language to its 2015 treatment drug court grant requirements to ensure that drug court clients will not be compelled to stop or be prevented from using medication if it is prescribed or dispensed consistent with a licensed prescriber's recommendation, a valid prescription, or as part of a regulated opioid treatment program.

SAMHSA regulates opioid treatment programs, which are expected to provide a full range of services for their patients. In collaboration with the Drug Enforcement Administration, SAMHSA provides waivers to physicians wishing to treat opioid use disorders with buprenorphine in a practice setting other than an opioid treatment program.

SAMHSA also funds efforts to help prevent prescription opioid misuse and heroin use. For example, in 2014, SAMHSA's Strategic Prevention Framework—Partnerships for Success program, made preventing and reducing heroin use one of its focus areas, along with prescription drug misuse and abuse, and underage drinking. For 2016, the President has proposed \$10 million for the Strategic Prevention Framework Rx, or SPF Rx, to help States use data, including PDMP data, to identify and assist communities at high risk for the nonmedical use of prescription drugs.

We want to thank you, again, for taking on this issue and for allowing SAMHSA an opportunity to share some of its efforts with you. We look forward to answering your questions.

[The prepared statement of Ms. Hyde follows:]



**Testimony Before the
House Energy and Commerce Oversight and Investigation Subcommittee
Hearing on "What is the Federal Government Doing to Combat the Opioid
Abuse Epidemic?"**

May 1, 2015

Statement of Pamela S. Hyde, J.D.

Administrator

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

Good morning Chairman Murphy, Ranking Member DeGette, and distinguished members of the Energy and Commerce Oversight and Investigation Subcommittee. My name is Pamela Hyde, and I am the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am pleased to address SAMHSA's role in preventing non-medical use of prescription opioids and treating individuals who abuse or misuse prescription opioids and heroin.

SAMHSA's Role

SAMHSA was established in 1992 and is directed by the Congress to effectively target substance abuse and mental health services to the people most in need of them and to translate research in these areas more effectively and more rapidly into the general health care system. Substance abuse, substance use disorders, poor emotional health, and mental illnesses take a toll on individuals, families, and communities. These conditions cost lives and productivity, and strain families and resources in the same way as untreated physical illnesses. SAMHSA works to focus the nation's attention on these preventable and treatable problems. Specifically, SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA strives to create awareness that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

SAMHSA supports the Secretary of Health and Human Services initiative to address opioid-related overdose, death, and dependence through our programs and initiatives that address three key areas: opioid prescribing practices, increasing use of naloxone, and expanding use of medication-assisted treatment (MAT).¹ In addition, SAMHSA's programs support the Office of National Drug Control Policy's (ONDCP) four-part Prescription Drug Abuse Prevention Plan. SAMHSA works across HHS through the Behavioral Health Coordinating Council's Prescription Drug Abuse Subcommittee. As a result, SAMHSA has partnerships with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services (CMS), the Office of the National Coordinator for Health Information Technology (ONC), the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Planning and Evaluation aimed at preventing and treating the non-medical use of prescription drugs. SAMHSA is also represented on the ONDCP Interagency Workgroup on Prescription Drug Abuse.

The challenges of the non-medical use of prescription opioids, as well as heroin abuse, are complex issues that require epidemiological surveillance, interventions, and access to further research. In addition, non-medical use of prescription opioids requires distribution chain integrity and prescriber education. No organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical and other health partners,

¹ Department of Health and Human Services. HHS Takes Strong Steps to Address Opioid-drug Related Overdose, Death and Dependence. March 26, 2015.
http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf

public health officials, state governments, and community organizations all are needed to implement educational outreach and intervention strategies targeted to a range of discrete audiences, including physicians, pharmacists, patients, educators, parents, high school and college students, adults at high risk, older adults, and many others. Outreach to prescribers, as well as pharmacists, on proper prescribing and dispensing of opioid pharmacotherapies needs to be complemented by education, screening, intervention, and treatment services for those who use heroin and/or prescription opioids non-medically.

What the Current Data Show

According to the 2013 National Survey of Drug Use and Health (NSDUH), which SAMHSA conducts annually, 4.8 million individuals (aged 12 and older) reported nonmedical use of opiates, including prescription pain relievers and heroin, during the past month.² That equals 2.6 percent of the U.S. civilian non-institutionalized population, of which 289,000 individuals reported past month use of heroin. Although the total number reporting heroin use is significantly lower than reported nonmedical use of prescription opiates, the numbers have been increasing fairly steadily since 2007 – both for past month use, as well as past year heroin use. In fact, past month heroin use more than doubled in five years from 161,000 individuals in 2007 to 335,000 in 2012. However, the number of people reporting past month use decreased to 289,000 in 2013.³

Of the individuals admitted to treatment in 2012, 285,451 (16.3 percent) people reported heroin as their primary drug of abuse. Another 169,868 (9.7 percent) people reported prescription opioids as their primary drug of abuse. This represents a 9.5 percent and a 2.5 percent increase respectively for the period 2005 to 2012.⁴

Opioid and Heroin Addiction Treatment

The challenge of addressing misuse of opioids cannot be met unless those needing treatment receive it. However, according to the 2013 NSDUH, only 10.9 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received treatment, which includes hospitals (inpatient only), drug or alcohol rehabilitation facilities (inpatient or outpatient), or mental health centers. It does not include treatment at an emergency room, private doctor's office, self-help group, prison or jail, or hospital as an outpatient.

² Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014. NOTE: NSDUH includes information on the use of illicit drugs, alcohol, and tobacco in the civilian, noninstitutionalized population of the United States aged 12 years old or older.

³ Id.

⁴ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2002-2012. National Admissions to Substance Abuse Treatment Services*. BHSIS Series S-71, HHS Publication No. (SMA) 14-4850. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014. Retrieved from http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_Treatment_Episode_Data_Set_National_Tables.htm

Of the barriers to receipt of treatment reported, the largest is the lack of recognition that treatment is needed. The 2013 NSDUH data show that 95.5 percent of those identified as needing treatment for dependence or misuse of an illicit drug did not receive that treatment because they did not feel they needed it.⁵ This emphasizes the need for increases in education and prevention programs. Another 2.9 percent felt they needed treatment but still did not seek it. And, even for those who seek treatment there are significant barriers. Barriers reported in the 2013 NSDUH findings include lack of health insurance coverage and inability to pay for treatment (37 percent).⁶ Another 8.2 percent of people seeking treatment had health insurance that did not offer coverage or did not cover the full cost for treatment. Other barriers reported included not knowing where to go for treatment (9.0 percent), not having any transportation or the hours were not convenient (8.0 percent), and fear of possible negative effects on their job (6.6 percent).⁷

SAMHSA's programs are designed to help provide treatment and services for people with substance use disorders (SUD), support the families of people with SUDs, foster supportive communities, and prevent costly behavioral health problems. Consistent with those aims, a number of SAMHSA's programs support the Secretary's initiative regarding expanding the use of medication-assisted treatment (MAT). For those addicted to opioids, MAT is an evidence-based method of treatment that has proven to be an important part of effective treatment for opioid use disorder, decreasing craving and withdrawal symptoms, blocking euphoria if relapse occurs, and augmenting the effect of counseling.⁸

In 2015, Congress appropriated to SAMHSA \$12 million to expand or enhance MAT and other clinically appropriate services for persons with opioid use disorders. The "Medication-Assisted Treatment for Prescription Drug and Opioid Addiction" (MAT-PDOA) grant program will target those states that have experienced the highest rates of admissions for treatment of opioid use disorders. Under MAT-PDOA states will fund at least two high-risk communities with the greatest need to improve or expand access to MAT services, with a focus on heroin and prescription opioids. Through this program, SAMHSA seeks to: 1) increase the number of individuals receiving MAT services, including screening, and case management; 2) increase the number of individuals receiving integrated care, including organized delivery and/or coordination of medical, behavioral or social and recovery support services; and 3) decrease illicit drug use at 6-months follow-up. MAT is to be provided in combination with comprehensive substance use disorder treatment, including but not limited to: counseling, behavioral therapies and when needed pharmacotherapy for co-occurring alcohol use disorder. The Administration has requested \$25.1 million for MAT-PDOA in the Fiscal Year (FY) 2016

⁵Substance Abuse and Mental Health Services Administration, NSDUH, Op cit.

⁶Id.

⁷Id.

⁸Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Methadone: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2; and Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Buprenorphine: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2. & Kraus et al., 2011; NIDA, 2012.

President's Budget (an increase of \$13.1 million over FY 2015). The proposed FY 2016 funding would increase the number of states receiving funding from 11 to 22 and would serve an additional 24 high-risk communities.

A number of other SAMHSA programs enhance access to opioid use disorder treatment, including MAT. Through the Pregnant and Postpartum Women's (PPW) initiative, SAMHSA encourages grantees to accept pregnant women with opioid addictions into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering MAT to their clients on-site while the women may be closely monitored and provided the medication as clinically appropriate. This results in women remaining in treatment longer, resulting in healthier births.⁹ Additionally, in SAMHSA's criminal justice programs – including the re-entry program – grantees are encouraged to use up to 20 percent of their grant awards for MAT.¹⁰ Finally, SAMHSA's Screening, Brief Intervention and Referral to Treatment (SBIRT) program provides screening for illicit drugs, including heroin and other opioids in primary care settings, hospital emergency rooms and trauma centers, and other community settings. To date, more than two million patients have received screening – with approximately 12 percent receiving a brief intervention, brief treatment, or referral to treatment.¹¹ To assist health care practitioners in understanding how to use SBIRT SAMHSA created the SBIRT Medical Residency and the Allied Health Professionals Training programs. These programs promote a multi-disciplinary team approach to the integration of behavioral health into medical health care. Each program includes prescription opioids and/or pain management/treatment modules. The curricula address identification of medication misuse and use of illicit substances and appropriate brief intervention and referral steps. To date, 6,629 medical residents and 14,502 nonresidents (e.g., physician assistants and psychologists) have been trained.¹²

The President's FY 2016 Budget proposes an additional \$20 million for a new program, the "Primary Care and Addiction Services Integration" program, which would enable substance use treatment providers to offer a full array of both physical health and substance use services to clients, including MAT. These grants would improve coordination and integration of services, improve quality, access, and reliability of healthcare to improve health outcomes and reduce the cost of care by controlling physical healthcare costs.¹³

SAMHSA also has primary responsibility for regulating Opioid Treatment Programs (OTPs). OTPs provide MAT and counseling services for opioid use disorders directly to their respective patients. OTPs must maintain certification with SAMHSA in order to operate. SAMHSA

⁹ Substance Abuse and Mental Health Services Administration (2014) *Preliminary Cross-site Data Analysis*

¹⁰ Grants to Expand Substance Abuse Treatment Capacity in Adult and Family Drug Courts, <http://www.samhsa.gov/grants/grant-announcements/ti-15-002>

¹¹ SAMHSA (2002–February 2015). The Services Accountability Improvement System. Retrieved on February 13, 2015 from <https://www.samhsa-grpa.samhsa.gov>

¹² Id.

¹³ Not only do people with substance use disorder experience health disparities in morbidity and mortality, Medicare and Medicaid cost data demonstrate that for people with multiple chronic conditions, costs are significantly higher when one of those conditions is a substance use disorder. Currently, a significant component of the overall higher cost of care for those with substance use disorder is untreated chronic disease. Boyd, C., Clark, R., Leff, B., Richards, T., Weiss, C., Wolff, J. (2011, August). *Clarifying Multimorbidity for Medicaid Programs to Improve Targeting and Delivering Clinical Services*. Presented to SAMHSA, Rockville, MD. & Barnett, P.G. (2009). Comparison of costs and utilization among buprenorphine and methadone patients. *Addiction*, 104, 982-992.

cooperates with state agencies, the Drug Enforcement Administration (DEA) and approved accrediting organizations to accomplish this. Currently there are 1,369 OTPs in operation, with an additional 59 pending SAMHSA certification.

Consistent with the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians wishing to treat opioid use disorders with buprenorphine in a practice setting not subject to Opioid Treatment Program regulations, such as a private practice or non-OTP treatment program, must request a waiver from SAMHSA. Initially physicians in these settings are restricted to treating a maximum of 30 patients at a time. After one year of experience with buprenorphine, physicians may choose to request that SAMHSA increase their patient limit to 100. SAMHSA coordinates both of these steps with the DEA. Of the approximately 877,000 physicians registered with the DEA to prescribe controlled substances, there are currently 29,194 physicians with a waiver to prescribe buprenorphine for opioid dependence. Of these, 9,011 (31 percent) are authorized to treat up to 100 patients. These 29,194 waivered physicians treated an estimated 1 million patients with buprenorphine mono- and buprenorphine/naloxone combination medications in 2012, which is a 62 fold increase since 2003.¹⁴

Recognizing that there is a need to further educate providers regarding the use of injectable extended-release naltrexone in addition to the more heavily regulated opioid agonist therapies, SAMHSA has developed a wide variety of educational and clinical practice guidelines. These include "Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorders: A Brief Guide" released in January 2015. SAMHSA also plans to convene a meeting on the use of opioid antagonist therapies in 2016 to bring together researchers, clinicians, and others specifically to review the literature and clinical experiences with naltrexone.

Preventing Opioid Misuse and Heroin Use

In support of the training and educational priority area of the Secretary's initiative, SAMHSA's prevention programs focus on educating providers and communities regarding opioid misuse and providing them with the tools to better identify and target at-risk populations.

Substance Abuse Prevention and Treatment Block Grant (SABG) state grantees are required to use at least 20 percent of their grant allotment on primary prevention strategies that target individuals in the general population and sub-groups that are at high risk for substance abuse. Many grantees use prevention funding to target the prevention of prescription drug and heroin use, particularly among youth. Over 80 percent (83.3 percent) of state grantees reported that they planned to use 2015 SABG funding to target prescription drug use prevention, making prescription drugs the second most targeted substance among state grantees. Additionally, more than one third of grantees (36.7 percent) reported that they planned to use 2015 SABG funding to target the prevention of heroin use.¹⁵ States will report on their progress throughout the fiscal year, and SAMHSA will continue to monitor their activity.

¹⁴ IMS, *Vector One®: Total Patient Tr.* as cited in Clark, H.W. (April 29, 2014), Testimony before the House Energy and Commerce Oversight and Investigation Subcommittee Hearing on Prescription Abuse and Heroin Abuse, p. 9

¹⁵ 2015 Substance Abuse Prevention and Treatment Block Grant Plan

The Strategic Prevention Framework - Partnerships for Success (SPF-PFS) grant program, one of SAMHSA's prevention initiatives, requires grantees to build capacity in communities of high need to address one or both of two national priorities: underage drinking among persons aged 12 to 20 and prescription drug misuse and abuse among persons aged 12 to 25. The FY 2014 SPF-PFS grantees were able to choose a third area of focus which may include preventing and reducing heroin use. The President's FY 2016 Budget proposes a new \$10 million initiative to combat the non-medical use of prescription drugs. "The Strategic Prevention Framework Rx" will provide funds to develop capacity and expertise in the use of data from state prescription drug monitoring programs to identify communities by geography and high-risk populations (e.g., age group), particularly those communities that are in need of primary and secondary prevention. Funding will support up to 20 state planning grants, technical assistance, and evaluation to build capacity to address prescription drug misuse, and overdose prevention efforts, in conjunction with other state and local partners. This initiative uses PDMP data to identify opportunities in communities for prevention programs, connecting patients to treatment resources and is designed to complement CDC's Prescription Drug Overdose: Prevention for States, which focuses on using PDMP data to affect prescribing behaviors of practitioners.

SAMHSA has also funded the "Not Worth the Risk, Even If It's Legal" education campaign, which encourages parents to talk to their teens about preventing prescription drug abuse. Another educational program, "Prevention of Prescription Abuse in the Workplace," is designed to support workplace-based prevention of misuse and abuse of prescription drugs for employers, employees, and their families.

SAMHSA also recognizes the importance of recovery and has included Recovery Support as one of our strategic initiatives. Recovery services are the clinically-based structured processes that coordinate and facilitate recovery after acute treatment. In March 2015, SAMHSA issued revised "Federal Guidelines for Opioid Treatment Programs," which include new guidance on recovery. According to the revised guidelines, OTPs should include recovery support services in their clients' treatment plans, either providing recovery support directly or via referral to adequate and accessible community services. With adequate treatment and recovery supports, recovery can and should be the expectation.

Opioid Overdose Prevention

SAMHSA has also developed tools to help educate first responders about naloxone, which support the Secretary's initiative regarding increasing the use of naloxone. When administered in a timely manner and effectively, naloxone rapidly restores breathing to a victim in the throes of an opioid overdose. Because police are often the first on the scene of an overdose, local law enforcement agencies can train and equip their personnel with naloxone as a means of improving response. SAMHSA has communicated to SABG grantees that, at the state's discretion, block grant funds may be used to support first-responder naloxone initiatives. For example, SABG primary prevention set-aside funds may be utilized to support overdose prevention education and training. Additionally, SABG funds other than primary prevention set-aside funds may be used to purchase naloxone and the necessary materials to assemble overdose kits as well as to cover the costs associated with the dissemination of such kits. However, SAMHSA encourages public and private insurers to pay for this medication for those at risk or for those living with people at risk.

SAMHSA also published an Opioid Overdose Prevention Toolkit in 2013 (updated in 2014) to educate individuals, families, first responders, prescribing providers, persons in recovery from substance abuse, and community members about steps to take to prevent opioid overdose and to treat overdoses (including the use of naloxone). The toolkit is the most downloaded document on the SAMHSA website, and SAMHSA continues to promote its availability through various social media outlets to reach a wide range of populations.

Additionally, the President's FY 2016 budget includes \$12 million for SAMHSA to fund "Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths," which will provide states with funds to purchase and distribute naloxone, equip first responders in high-risk communities, support education on the use of naloxone and other overdose death prevention strategies, and cover expenses incurred in disseminating overdose kits.

Finally, SAMHSA alerted the treatment community and the general public in 2014 about the marked increase in deaths reportedly linked to the use of heroin contaminated with clandestinely produced fentanyl has been noted.¹⁶ Fentanyl is a synthetic opiate analgesic and when used in combination with heroin can rapidly cause respiratory depression that can lead to respiratory arrest and even death. These deaths underline the need for increased access to overdose rescue medications.

Prescriber Education

According to 2012-2013 NSDUH data, 68 percent of those who used pain relievers non-medically in the past year obtained them from a friend or relative.¹⁷ About 84 percent of those relatives or friends each obtained their medications from a single doctor. While many individuals prescribed opioids may have a legitimate need for pain relievers, it is essential for prescribers to reduce inappropriate prescribing and for patients to know how to use and dispose of their medications. Therefore, a core aspect of the Secretary's initiative – to provide guidance around appropriate opioid prescribing practices – focuses on unnecessary or excessive prescribing.

SAMHSA has developed a series of medical education courses designed to help physicians provide appropriate pain management while minimizing the risk of pain medication misuse. SAMHSA is partnering with CDC in its development of the CDC Opioid Prescribing Guidelines for Chronic Pain. Together with CDC, SAMHSA will help disseminate and encourage uptake of the new guidelines. In addition, SAMHSA has partnered with Boston University School of Medicine and the Massachusetts Board of Medicine to develop a series of free, online courses on prescribing for pain. More than 62,000 certificates of completion have been issued since the inception of this program.¹⁸ SAMHSA also offers live Continuing Medical Education courses in partnership with state health departments, medical societies, licensing boards, schools, and state

¹⁶ SAMHSA (February 7, 2014) *SAMHSA issues Advisory to treatment community on the danger of heroin contaminated with fentanyl and what can be done to save lives*, <http://www.samhsa.gov/newsroom/press-announcements/201402071000>

¹⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

¹⁸ Boston University School of Medicine, www.opioidprescribing.com

Prescription Drug Monitoring Programs (PDMPs), as well as special courses for the Indian Health Service, community health centers, and U.S. military hospitals. SAMHSA supports training in the use of all FDA-approved medications for the treatment of opioid use disorders via the Physician Clinical Support System for Medication Assisted Treatment. SAMHSA also funds the Prescribers' Clinical Support System for Opioid Therapies, a collaborative project led by American Academy of Addiction Psychiatry with six other leading medical societies. Program tools focus on the safe use of opioids in treatment of pain, including training on how to recognize non-medical, misuse, and dependence in those with pain.

Prescription Drug Monitoring Programs

In 2011, SAMHSA initiated the Enhancing Access to Prescription Drug Monitoring Programs (PDMPs) Project, which uses health information technology to improve access to PDMPs in an effort to reduce prescription drug misuse and overdose. The project was funded by SAMHSA and managed by the Office of the National Coordinator for Health Information Technology in collaboration with SAMHSA, CDC, and ONDCP. SAMHSA also funded the PDMP EHR Integration and Interoperability Cooperative Agreement program in FY 2012 and the Electronic Health Record and PDMP Data Integration Cooperative Agreement in FY 2013. These programs bring funding directly to states to complete integration projects. These cooperative agreements build upon previous efforts by increasing scale and integration implementation throughout the states. Most of the first cohort grantees have been able to integrate their state PDMPs into health information exchanges and EHRs and expand interoperability with other states.

SAMHSA's activities in this area complement CDC's activities to maximize the use of state-based PDMPs as a public health tool to assist in clinical decision-making and in conducting public health surveillance. They also complement ONC's Enhancing Access to PDMPs Using Health IT Project and S&I Framework Initiative, which focuses on exploring and pilot testing technical standards to enable data exchange between PDMPs and Health IT systems. This has not been done previously and may facilitate more widespread use of PDMPs by prescribers and pharmacists who will be able to obtain PDMP data securely and easily from the IT systems they use daily to support prescribing decisions.

Conclusion

Prescription opioid misuse and heroin use are complex issues. They require a concerted and coordinated effort across HHS and the Federal Government. SAMHSA's prevention and treatment strategies to address drug misuse are both targeted specifically to the drugs themselves and to programs that support prevention, intervention, and treatment of substance use disorders, which can have a significant long-term impact on this serious public health problem. Through these and other educational and public service activities, SAMHSA continues to focus on our mission of reducing the impact of substance abuse and mental illness on America's communities while collaborating with our sister agencies and partners within and outside of the Federal Government.

Thank you for this opportunity. I welcome any questions that you may have.

Mr. MURPHY. Thank you, Ms. Hyde.
Dr. Conway, you're recognized for 5 minutes.

STATEMENT OF PATRICK CONWAY

Dr. CONWAY. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for inviting me to discuss the CMS's work to ensure that all Medicare and Medicaid beneficiaries are receiving the medicines they need, while also reducing and preventing prescription drug abuse.

As we have heard from other witnesses, opioid analgesics have increasingly been implicated in drug overdose deaths over the last decade. As a practicing physician, I understand the importance of this issue.

CMS recognizes our responsibility to protect the health of Medicare and Medicaid beneficiaries by ensuring that appropriate safeguards are in place to help prevent overuse and abuse of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments for substance abuse disorder.

Since its inception in 2006, the Medicare part D prescription drug benefit has made medicines more available and affordable, leading to improvements in access to prescription drugs and better health outcomes.

Despite these successes, part D is not immune from the nationwide epidemic of opioid abuse. CMS has broadened its initial focus of strengthening beneficiary access to prescribed drugs to also address potential fraud and drug abuse by making sure part D sponsors implement effective safeguards and provide coverage for drug therapies that meet safety and efficacy standards.

We believe that broader reforms that result in better coordinated care will help protect beneficiaries from the damaging effects associated with prescription drug abuse and to prevent and detect overutilization related to prescription drugs.

A centerpiece of our strategy is to strengthen CMS's monitoring of part D plan sponsors' drug utilization management programs, to prevent overutilization of these medications. To accomplish this goal, the Medicare part D overutilization monitoring system, or OMS, was implemented in 2013. Through this system, CMS provides reports to sponsors on beneficiaries with potential opioid overutilization identified through analysis of prescription drug event data and through beneficiaries referred by the CMS Center for Program Integrity. Sponsors are expected to utilize various drug utilization monitoring tools to prevent continued overutilization of opioids. Recent data has shown that from 2011 to 2014, the OMS has reduced the number of potential opioid over-utilizers by appropriately 26 percent.

CMS also utilizes the Drug Integrity Contract, or MEDIC, which is charged with identifying and investigating potential fraud and abuse, and developing cases for referral to law enforcement agencies. In 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in part D. CMS has also used our rule-making authority to create new tools to take action against problematic prescribers and pharmacies. We recently finalized a provision that requires prescribers of part D drugs to enroll or have a valid opt-

out affidavit on file, and establishes a new revocation authority for abusing prescribing patterns.

State Medicaid agencies have also taken action to tackle the opioid abuse epidemic. Efforts include expanding the Medicaid benefit to include behavioral health services for those with addiction to prescription drugs and pharmacy management review programs. Although CMS does not determine what services are provided in each Medicaid program to prevent and treat opioid abuse, we are encouraged by the increasing efforts by States to develop effective strategies for designing benefits for this population.

We recently launched the Medicaid Innovation Accelerator Program, or IAP, to provide States with technical assistance and other types of support to address this important issue.

CMS, in coordination with CDC, SAMHSA, and NIH, issued an informational bulletin on medication-assisted treatment for Substance Abuse Disorder in the Medicaid program. This guidance outlines that a combination of medication and behavioral therapies is the most effective combination of treatment. We issued a similar bulletin focused on these services in the pediatric and youth population.

CMS is dedicated to providing the best possible care to beneficiaries with opioid addiction, and is working with part D sponsors and State Medicaid programs to implement effective safeguards to prevent opioid abuse and treat patients effectively with substance abuse disorders.

CMS has made progress, but there is more work to be done. CMS is undertaking multiple policy initiatives and interventions to reduce the rate of opioid addiction and overdoses in both Medicare and Medicaid.

In previous testimonies, I've never had family here or the time to thank them, so I do want to thank my mother, Diane Conway, is here and my son, Jack, who's out of school, as well as my wonderful wife, Heather, and daughters Alexa and Savannah. And without their love and support, I would not be able to work on issues like this that are critically important to our Nation. So thank you.

[The prepared statement of Dr. Conway follows:]

STATEMENT OF

PATRICK CONWAY, M.D., MSc
ACTING PRINCIPAL DEPUTY ADMINISTRATOR,
DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY, AND
CHIEF MEDICAL OFFICER,
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

“WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT THE OPIOID
ABUSE EPIDEMIC?”

BEFORE THE
UNITED STATES HOUSE COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS

MAY 1, 2015

**Statement of Patrick Conway, M.D., MSc on
“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”
U.S. House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
May 1, 2015**

Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) work to ensure that all Medicare and Medicaid beneficiaries are receiving the medicines they need while also reducing and preventing prescription drug abuse.

Prescription drugs, especially opioid analgesics—a class of prescription drugs used to treat both acute and chronic pain such as hydrocodone, oxycodone, codeine, morphine, and methadone, have increasingly been implicated in drug overdose deaths over the last decade. Deaths related to heroin have also sharply increased since 2010, with a 39 percent increase between 2012 and 2013. Among drug overdose deaths in 2013, approximately 37 percent involved prescription opioids.¹ In 2013 drug overdose was the leading cause of injury death² and caused more deaths than motor vehicle crashes among individuals 25-64 years old.³ The monetary costs and associated collateral impact to society due to Substance Use Disorder (SUD) are high. In 2009, health insurance payers spent \$24 billion for treating SUDs, of which Medicaid accounted for 21 percent of spending.⁴ The Medicare program, through Part D, spent \$2.7 billion on opioids overall in 2011, of which \$1.9 billion (69 percent) was accounted for by opioid users with spending in the top five percent.⁵

¹ Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013 from <http://www.cdc.gov/drugoverdose/index.html>

² Injury deaths are those caused by acute exposure to physical agents, e.g., mechanical force or energy, heat, electricity, chemicals, and ionizing radiation, in amounts or at rates that exceed the threshold of human tolerance, http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_10.pdf

³ Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013, <http://www.cdc.gov/homeandrecreationsafety/overdose/facts.html>

⁴ Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013 from <http://www.cdc.gov/drugoverdose/index.html>

⁵ Suzuki, Shinobu. Potentially Inappropriate Opioid Use in Medicare Part D. MEDPAC. October 9, 2014. <http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-.pdf?sfvrsn=0>

CMS has a responsibility to protect the health of Medicare and Medicaid beneficiaries, by putting appropriate safeguards in place to help prevent overuse and abuse of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments for SUD.

Preventing Overprescribing and Abuse of Opioids in Medicare Part D

Since its inception in 2006, the Medicare Part D prescription drug benefit program has made medicines more available and affordable for over 55 million Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage.

Despite these successes, Part D is not immune from the nationwide epidemic of opioid abuse. Based on input from the Department of Health and Human Services' Office of the Inspector General (HHS OIG), the Government Accountability Office (GAO), and stakeholders, over the past several years, CMS has broadened its initial focus of strengthening beneficiary access to prescribed drugs to also address fraud and drug abuse by making sure Part D sponsors implement effective safeguards and provide coverage for drug therapies that meet safety and efficacy standards. The structure of the program, in which Part D plan sponsors do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees, makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing or dispensing patterns relative to the entire Part D program. CMS is aware of potential fraud at the prescriber and pharmacy levels through "pill mill" schemes. This is a term used by local and state investigators to describe a physician, clinic, or pharmacy that is prescribing or dispensing opioids for non-medical and inappropriate purposes. We believe that broader reforms that result in better-coordinated care will help address several issues with the complex health care delivery system, including abuse of prescription drugs. CMS has, however, taken several steps to protect beneficiaries from the harm and damaging effects associated with prescription drug abuse and to prevent and detect fraud related to prescription drugs.

A centerpiece of our strategy to reduce the inappropriate use of opioid analgesics in Part D is the adoption of a policy and guidance by CMS by which Part D sponsors identify Part D enrollees who have potential opioid or acetaminophen overutilization that may present a serious threat to patient safety. Acetaminophen is included in this strategy because it is manufactured in

combination with many opioids, and unlike opioids has an FDA-approved maximum daily dose. Overutilization of opioids or acetaminophen products can result in serious adverse events including death. To strengthen CMS's monitoring of Part D plan sponsors' drug utilization management programs to prevent overutilization of these medications, the Medicare Part D Overutilization Monitoring System (OMS) was implemented in 2013. Through this system, CMS provides quarterly reports to sponsors on beneficiaries with potential opioid or acetaminophen overutilization identified through analyses of Prescription Drug Event (PDE) data and through beneficiaries referred by the CMS Center for Program Integrity (CPI). Sponsors are expected to utilize various drug utilization monitoring (DUM) tools, including: formulary-level controls at point of sale (such as safety edits and quantity limits); a review of previous claim and clinical activity to identify at-risk beneficiaries, case management outreach to beneficiaries' prescribers and pharmacies, and beneficiary-level point of sale claim edits, if necessary to prevent continued overutilization of opioids. Lastly, sponsors that have concluded such point of sale edits are appropriate are expected to share information with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

We believe this Part D overutilization policy has played a key role in reducing opioid and acetaminophen overutilization in the program. A comparison of overutilization shows a significant reduction of opioid and acetaminophen overutilization in Part D since the overutilization policy went into effect. From 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS, decreased by approximately by approximately 26 percent, or 7,500 beneficiaries⁶. In addition, from 2011 through 2014, the number of beneficiaries identified as potential acetaminophen overutilizers, based on the CMS definition in the OMS, decreased by more than 91 percent, or 70,000 beneficiaries.⁷

CMS also contracts with the Medicare Drug Integrity Contractor (MEDIC), which is charged with identifying and investigating potential fraud and abuse, and developing cases for referral to law enforcement agencies. In September 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in Part D. As a result, the MEDIC identified vulnerabilities and then

⁶ There were 29,404 potential opioid overutilizers, (or 0.29% of all Part D opioid users) in 2011 and there were 21,838 potential opioid overutilizers, (0.18% of all Part D Opioid users) in 2014

⁷ There were 76,581 potential acetaminophen overutilizers, (or 0.81% of all Part D acetaminophen users), in 2011 and in 2014 there were 6,286 (0.06% of all Part D acetaminophen users) in 2014

performed analyses that resulted in notification to plan sponsors to remove records associated with inaccurate data leading to improper payments made in FYs 2011 and 2012. This increased focus on proactive analysis resulted in savings of \$4.8 million from decreased provider payments, \$21 million for unallowable charges for medications during a hospice stay, and \$80 million for Transmucosal Immediate Release Fentanyl drugs without a medically-acceptable indication.

CMS has new tools to take action against problematic prescribers and pharmacies. CMS issued a Final Rule on May 23, 2014, that both requires prescribers of Part D drugs to enroll in Medicare or have a valid opt-out affidavit on file and establishes a new revocation authority for abusive prescribing patterns. Additionally, CMS may now also revoke a prescriber's Medicare enrollment if his or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked, or the applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

Last year, CMS finalized a rule⁸ that includes a provision to give CMS, its antifraud contractors, and the Government Accountability Office (GAO) the ability to request and collect information directly from pharmacy benefit managers, pharmacies and other entities that contract or subcontract with Part D Sponsors to administer the Medicare prescription drug benefit. The provision streamlines CMS' and its anti-fraud contractors' investigative processes. Previously, it took a long time for CMS' contractors who were often assisting law enforcement to obtain important documents like invoices and prescriptions directly from pharmacies, because they worked through the Part D plan sponsor to obtain this information. This provision provides more timely access to records, including for investigations of Part D fraud and abuse, and responds to recommendations from the Department of Health and Human Services (HHS) Office of Inspector General.

⁸ Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, <https://www.federalregister.gov/articles/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the>

In addition to these initiatives, the FY 2016 President's Budget⁹ includes several proposals that would provide CMS with additional tools to prevent inappropriate use of opioids. One proposal to prevent prescription drug abuse in Medicare Part D would give the Secretary of Health and Human Services (HHS) the authority to establish a program that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to many State Medicaid programs. The Medicare program would be required to ensure that beneficiaries retain reasonable access to services of adequate quality. Currently, CMS requires Part D sponsors to conduct drug utilization reviews, which assess the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. However, CMS' statutory authority to take preventive measures in response to this information is limited.

The FY 2016 President's Budget also proposes to provide the Secretary with new authorities to: (1) suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential; (2) suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients; and (3) require additional information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. While Part D sponsors have the authority to deny coverage for a prescription drug on the basis of lack of medical necessity, there are currently no objective criteria to inform the medical necessity determination, such as maximum daily dosages, for some controlled substances, especially opioids. Therefore, the only basis for establishing medical necessity in these cases is prescriber attestation. If the integrity of the prescriber is compromised, the finding of medical necessity is compromised as well. If the Secretary had clear authority to intervene in these patterns suggestive of abusive prescribing or harmful medical care, the incidence of coverage and payment of such questionable prescribing could be reduced in Medicare.

Preventing Overprescribing and Abuse of Opioids in Medicaid

⁹ Fiscal Year 2016 Budget in Brief, <http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html>

Many State Medicaid Agencies have started using a variety of approaches to prevent prescription drug abuse. These efforts include expanding the Medicaid benefit to include behavioral health services for those with an addiction to prescription drugs, and provider enrollment and monitoring to ensure providers are appropriately evaluated upon initial enrollment and reevaluated in years following. States are also using pharmacy management review and restriction programs which confine patients with high-utilization of prescription pain medication to a single provider and pharmacy.

The FY 2016 President's Budget proposes requiring states to track high prescribers and utilizers of prescription drugs in Medicaid. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. Under this proposal, states would be required to monitor high risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States could choose one or more drug classes and would need to develop or review and update their care plan to reduce utilization and remediate preventable episodes to improve Medicaid integrity and beneficiary quality of care.

Partnering with States to Improve Access to Care

In addition to efforts to prevent opioid abuse, CMS is committed to meeting the needs for Medicare and Medicaid beneficiaries seeking treatment for addiction. Although CMS does not determine what services are provided in each State Medicaid program to prevent and treat opioid abuse, CMS is encouraged by the increased efforts by States to develop effective strategies for designing benefits for this population. Many States have included behavioral health services for individuals with substance use disorders (SUDs) in their State Plans and various Medicaid managed-care organizations (MCOs) or in Waiver programs. CMS recently released a Notice of Proposed Rule Making regarding the application of the Mental Health Parity and Addiction Equity Act to the Medicaid and Children's Health Insurance Program.¹⁰ The NPRM seeks to

¹⁰ Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans, <https://www.federalregister.gov/articles/2015/04/10/2015-08135/medicaid-and-childrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of>

make sure that MCOs' and states' benefit limitations on mental health and substance use disorder benefits are no more restrictive than those on medical/surgical benefits.

CMS also launched the Medicaid Innovation Accelerator Program (IAP) in July 2014 with the goal of improving health and health care for Medicaid beneficiaries by supporting states' efforts to accelerate new payment and service delivery reforms. The IAP will enhance CMS's wide ranging efforts to improve care by supporting system-wide payment and delivery system reform innovation. Through the IAP, states receive technical assistance and other types of technical support designed to accelerate the development and testing of Substance Use Disorder (SUD) service delivery innovations including efforts to curb prescription drug abuse. Strategies being pursued include:

- Payment and health care delivery models: Identify successful service delivery models, benefit strategies, and payment methodologies to promote improved care and better coordination between individuals with SUDs and health care systems;
- Data analytics: Support states in using data to better understand the needs of the Medicaid populations that have a SUD or that are at-risk of developing a SUD;
- Quality measurement: Collect and test metrics that support states in more accurately measuring improvements in health outcomes for individuals with SUDs;
- Rapid-cycle learning: Assist states in understanding how to integrate elements of rapid-cycle learning as part of their SUD-related projects; and
- State to state learning: Lesson sharing interventions used by other states.

States can get involved in the IAP SUD work in three different ways:

- The High-Intensity Learning Collaborative (HILC) is a year-long technical assistance initiative designed to support a small number of States in developing the necessary policy and infrastructure changes to improve care and outcomes for individuals with SUDs.
- Targeted Learning Opportunities (TLO) is a web-based learning series designed to support States in developing strategies for improving their SUD systems.
- National Dissemination provides access to materials including webinars, lessons learned, and other resources developed for the HILC and TLO that have been adapted for distribution.

To date, over 35 states have participated in Targeted Learning Opportunities (TLO) learning sessions. Seven states comprise the year-long High Intensity Learning Collaborative (HILC)¹¹. HILC states are actively working with CMS and experts to conduct data analytics, track quality measures, improve SUD benefits and service delivery, and explore value-based payment models as part of an overall effort to improve care and outcomes for individuals with SUDs. Several of these states, including Kentucky, Pennsylvania, Louisiana, and Michigan, are especially focused on reducing opioid dependence through their work in IAP.

As part of this initiative, CMS, in coordination with CDC, SAMSHA, and NIH, issued an informational bulletin on Medication Assisted Treatment (MAT) for Substance Use Disorders in the Medicaid program.¹² This informational bulletin provides background information about MAT, examples of state-based initiatives, and useful resources for states to help ensure proper delivery of these services.

To improve outcomes, the three medications that have received FDA-approval for treating opioid use disorders, Methadone, Buprenorphine, and Naltrexone, are recommended to be combined with behavioral therapies. Research shows that when treating SUDs, a combination of medication and behavioral therapies is the most effective combination of treatment. Behavioral therapies help patients engage in the treatment process, modify their attitudes and behaviors related to drug and alcohol abuse, and increase healthy life skills. These treatments can also enhance the effectiveness of medications and help people stay in treatment longer. While State Medicaid programs are not required to include all drugs on their preferred drug lists, we encourage states to understand the value of MAT and improving access to substance use disorder treatment medicines.

State Medicaid programs have used a variety of innovative approaches to treat beneficiaries with SUD. For example, last year, Vermont received approval to implement a Medicaid health home program that provides specialized treatment and recovery services to beneficiaries with SUDs. States may also utilize processes to help manage the prescribing of addiction medications and delivery of evidence-based behavioral therapies, including prior authorization, documentation of

¹¹ States participating in HILC are Kentucky, Louisiana, Michigan, Minnesota, Pennsylvania, Texas and Washington.

¹² CMS Informational Bulletin, “Medication Assisted Treatment for Substance Use Disorders”, July 11, 2015, <http://medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf>

behavioral therapy, and quality or duration limits. States should ensure that these strategies are consistent with the Mental Health Parity and Addiction Equity Act, when appropriate.

In January, CMS released an additional informational bulletin¹³ on behavioral health services available to youth with SUDs, including opioid use disorders. This bulletin is intended to assist States to design a benefit that will meet the needs of youth with SUDs and their families and helps States comply with Medicaid requirements. These services include: screenings and assessments to identify, address and create care plans as early as possible; outpatient treatments such as individual and group counseling to assist a beneficiary in achieving specific objectives of treatment or care; medication-assisted treatment to prevent, stabilize or ameliorate symptoms arising from treatment; recovery services and supports, such as peer-to-peer mentoring, to educate and support a patient to successfully make behavioral changes necessary to recover; and residential treatment programs that offer a planned and structured regimen of care in a residential setting.¹⁴

Conclusion

CMS is dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically appropriate care. CMS has broadened its focus from ensuring beneficiaries have access to prescribed drugs to ensuring that Part D sponsors and State Medicaid programs implement effective safeguards and provide coverage for drug therapies that meet standards for safety and efficacy. Although there is still work that needs to be done, CMS is confident that our initiatives will help to reduce the rate of opioid addiction and overdoses in both Medicare and Medicaid.

¹³ CMCS Informational Bulletin, “Coverage of Behavioral Health Services for Youth with Substance Abuse”, January 26, 2015, <http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf>

¹⁴ CMCS Informational Bulletin, “Coverage of Behavioral Health Services for Youth with Substance Abuse”, January 26, 2015, <http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf>

Mr. MURPHY. Thank you, Doctor. And thank you for recognizing Take Your Family to Testifying Day. Apparently everybody else did not get the memo.

I just want to start out by saying if talent and dedication alone could solve this crisis, we'd be there with the testimony of today and other days, but obviously, we still have problems. So let me start off with asking a few questions.

First, for Director Botticelli, for the Office of National Drug Control Policy, or ONDCP, uses the term "recovery," does it mean to include patients with opioid addiction in a buprenorphine or methadone treatment program and still using heroin or other illicit drugs, or would you say that's not recovery?

Mr. BOTTICELLI. So I think, you know, from our perspective, and also as a person in recovery, clearly we want to make sure that people are continuing to progress in their recovery, and that kind of freedom from substances is the ultimate goal of recovery programs, and I think everyone would agree on that, but we also know that substance use, and particularly opioid use disorders, are a significant chronic disorder, and that oftentimes, and even my own experience show me, that people often will experience relapse and will often, I think, need multiple attempts at treatment to get to that final goal of long-term recovery and long-term abstinence.

And so we really want to make sure that we're continuing to engage with patients, that we're moving them toward better health, better recovery, and being free from substance abuse as part of long-term recovery.

Mr. MURPHY. Well, let me ask in context of this, because we also heard from testifiers last week they felt there was not a uniform definition of recovery, but, I mean, this is the talent pool here, you're the ones that do these. Do you all meet on a regular basis to talk about these issues? And when was the last time you all got together to talk about policy issues? Was it within the last—can someone answer that? Pam? Pam Hyde?

Mr. BOTTICELLI. So let me start.

Mr. MURPHY. Oh, you will start? OK.

Mr. BOTTICELLI. Let me start with that, because it's actually part of our statutory authority—

Mr. MURPHY. OK.

Mr. BOTTICELLI (continuing). That we set in conjunction with, not just our HHS partners, but with all of the Federal agencies that have a role in substance use, and particularly in opioid use disorders. We have been engaged with the DOD and the VA and the Bureau of Prisons.

Mr. MURPHY. So you all meet regularly?

Mr. BOTTICELLI. We actually do meet regularly. So we have quarterly meetings to focus on where we are.

Mr. MURPHY. Well, let me move on that too, because that's going to be important.

Ms. Hyde, let me ask you a question here in your response to our bipartisan letter of March 18 concerning the National Registry of Evidence-Based programs, you noted that, quote, "new submission and review procedures will improve the rigor of the registry and bring NREPP into closer alignment with other registries of evidence-based programs in the Federal Government."

Now, prior to entering into this July 2014 contract, did SAMHSA feel that the scientific basis of the rigor of NREPP needed to be strengthened, yes or no? I mean, do you feel it needed to be strengthened?

Ms. HYDE. Thank you for the question. We thought the process that we used for determining what practices were reviewed needed to be strengthened, and in the process, we have also increased the rigor with which we look at them.

Mr. MURPHY. Can you get us a list, not today, but can you get us a list of what you consider to be some of the models within the Federal registry that we can review as part of that, as evidence-based programs?

Ms. HYDE. Certainly.

Mr. MURPHY. OK. Thank you.

Your response also indicates an outside contractor will assume the role of gatekeeper for NREPP, determining which studies and outcomes are reviewed in the screening and review of an intervention, with the aim of preventing bias in favor of the intervention developers.

Was SAMHSA's prior system for vetting and selecting interventions to be included in the NREPP prone to any kind developer bias or conflict of interest? Was that a concern?

Ms. HYDE. Yes, Mr. Murphy, it was a concern. It was pretty much developer driven. So a developer had to want their practice to be reviewed, and then they had some control over what research we looked at. We have changed that with the new contract, which began last year, and we will help decide priorities together with the public input, but the contractor will help us look more objectively at evidence.

Mr. MURPHY. Thank you. I just pulled up here—I just got a note, actually an article that, was this one of your constituents, Dr. Frank, from eastern Colorado? I don't want to take all your Colorado thunder, but it was fascinating article, because it made reference to the increased use of emergency departments associated with opiates. And it's interesting, they said that the reasons for this is—first of all, they said there's 10–1/2 million estimated people with this, it's probably an underestimate, that people go to the emergency rooms for treatment for withdrawal, but also many trying to get more opiates; and that when you have users with opiate prescriptions from more than one physician, they're more likely to be involved in riskier practices.

I wonder if any of you could comment on if that's an area that we're trying to address. I think, Dr. Volkow, you were also talking about issues with regard to prescribing practices, and Dr. Frank. Can some of you comment on those issues?

Dr. VOLKOW. Yes. And I think that that article, I think, that you're referring to the New England Journal of Medicine article that shows that there's been a very significant, quadruple number of cases of neonatal abstinence syndrome in the intensive care units, and this does reflect the fact that many women are actually being prescribed opioid medications during the pregnancy itself. And, actually, based on another study, it was estimated that 21 percent of women that are pregnant are going to receive an opioid medication, which, again, highlights the need to enforce better that

the guidelines on the management of pain need to be enforced in better ways. And this is also recognized by studies that have actually evaluated the extent to which physicians are following guidelines by the main medical organizations as it relates to the management of pain. So that is an area where there needs to be an aggressive increase in the education and enforcement of guidelines.

Mr. MURPHY. Thank you. I'm out of time. I'd just ask unanimous consent that I can submit this research article for the record.

[The information appears at the conclusion of the hearing.]

Mr. MURPHY. Ms. DeGette, you're recognized for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Volkow, as I mentioned in my opening statement, you're one of the world's top experts on the issue of treating addiction. Briefly, what does the body of scientific evidence show regarding the effectiveness of methadone and buprenorphine in this treatment of opioid abuse disorders?

Dr. VOLKOW. What the research has shown—and it has shown it not just for methadone and buprenorphine, but a more recent medication, naltrexone—is that these medications when used as part of a comprehensive program for the treatment of opioid addiction are quite effective, and they significantly improve the outcomes of individuals being able to stay, on the one hand, abstinent from the drug or to decrease the likelihood of relapsing, but it also protects them against the adverse outcomes, such as overdoses.

Ms. DEGETTE. So in light of those studies, you also said in your testimony that existing evidence-based prevention and treatment strategies are highly underutilized across the United States. And last week we had an expert tell our panel that very few patients with opioid addiction today receive treatments that have been proven most effective. He was talking about this rapid detox followed by abstinence-based treatment.

I'm wondering, Dr. Volkow, if you can help understand this. Why do we have a situation where people are not getting evidence-based treatment?

Dr. VOLKOW. Well, one of the problems has been—and it's a complex problem and there are many reasons why they're not getting the correct treatment, including the fact of adequate education as it relates to the proper screening and management of substance abuse disorder, including the healthcare system. Then you have a whole infrastructure that has developed because addiction is stigmatized, so, therefore, the likelihood of people accessing that medical care is much lower. And then, of course, there is a difference between States in the way that they implement the treatment. So all of these factors account for the current situation.

Ms. DEGETTE. Dr. Frank, do you have anything to add to that?

Dr. FRANK. Yes, I do. I think that one thing that's very important to remember is that overall, we treat 10 percent of the people with these disorders, so it's not surprising that people aren't getting evidence-based treatment, because they're not getting treatment, period.

Second part is why aren't they getting evidence-based treatment among those who do? And I think that there are insurance dynamics that hopefully we're fixing, there are, as Dr. Volkow said, access to trained professionals who are trained in the best things, and

then there's, in a sense, trying to kind of get the systems and the infrastructures aligned so that they support the best practices.

Ms. DEGETTE. And, Dr. Houry, several of our witnesses, including you, mentioned the role of the States in this. Can you talk about that for a minute?

Dr. HOURY. Absolutely. I think States have different populations, different issues, different prescription drug monitoring programs, and so tailoring these programs for States so they can best identify, whether it's their State Medicaid program, other high-risk programs or patients and how to best target them, and that's why the program at the CDC is really helpful, because we have the higher level view to work across the States for this.

Ms. DEGETTE. And do you think the States have work to do in terms of implementing these programs that are science-based and that work?

Dr. HOURY. You know, I think we're starting to do that. Like, our program itself has only been in existence for 6 months, but we're seeing great progress. And if you look at some of the policies that States are implementing, we're seeing reductions in what we call doctor shopping and patients going to different doctors, because of utilizing prescription drug monitoring programs. So although it's early in the stage, I'm very optimistic that we are making progress in the States.

Ms. DEGETTE. OK. Dr. Volkow, I want to come back to you. One of our other experts last week said patients and their families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse.

I'm wondering if you can tell us what the science shows. Is this type of treatment generally effective or less effective? What does the research show?

Dr. VOLKOW. The research has shown that in general, fast detoxification of patients is associated with increased mortality, like what you just mentioned. And this reflects the fact that addiction is a chronic disease and the changes that occur in the brain persist months, years after you've stopped taking the drug.

So what they do in this fast detoxification is just remove the physical dependence and assume that the addiction is cured, and these are two independent processes, and as a result of that, the patient feels that they are safe and then they relapse because they are still addicted—

Ms. DEGETTE. Thank you.

Dr. VOLKOW (continuing). And many times they overdose.

Ms. DEGETTE. Thank you.

Thank you very much, Mr. Chairman.

Mr. MURPHY. I now recognize Mr. Collins for 5 minutes.

Mr. COLLINS. Thank you, Mr. Chairman. This is truly a fascinating topic we're discussing, and it's obvious there's no very easy solution. I mean, we've heard it's a chronic disease, 10 percent are seeking treatment. I guess my question maybe for Ms. Hyde at SAMHSA is, you know, certainly with pregnant women that may have young kids at home, and inpatient treatment might be the preferred, and we just can't let perfect be the enemy of good, what other options are you looking at for people who can't get in, I mean, they're just not going to enter inpatient, so they may be part of the

90 percent not getting treatment at all? Some treatment better than no treatment, as frustrating as that might be? What are your comments to the young mother that's got kids at home and she's pregnant and she's dependent and she just can't go into an inpatient center? What do we do for that patient?

Ms. HYDE. Thank you for the question. The issue of pregnant and parenting women is a big one in our field. We do have a small program to address that issue, but you're right, it's a residentiallybased program.

We have increasingly been looking at ways to take what we learn in that program about the best ways to treat pregnant and parenting women and take it into other settings, so whether it's our opioid treatment programs or the training that we do for physicians who are using medication-assisted treatment to deal with pregnant and parenting women. So we're trying in every way that we can to make those services available to those women.

Mr. COLLINS. So, again, with pregnant women, and we're looking at other treatments, I guess, whether that's buprenorphine or methadone, are there studies that show whether that has an impact on the fetus and the baby?

Ms. HYDE. You're right to be concerned about the child. What we see is that this prevents death, it prevents addiction of the baby, it prevents a lot of other issues that may come with allowing the young woman to continue with the illicit drug use or the prescription opioid misuse. So definitely providing treatment helps both the woman and the child.

Mr. COLLINS. Now, as you've counseled these women, what kind of reaction are you getting? Are they recognizing—and you would think the genuine concern they have for the baby. I mean, there's very much a complicated balancing act going on here. What kind of reactions are you getting from the women acknowledging the problem and wanting to treat it?

Ms. HYDE. You know, most pregnant and parenting women really want to do the best thing for their babies, and they want to do the best thing for themselves, but as you've heard, addiction is a chronic disease and it's very difficult; changes the brain, changes the ability to make decisions.

The women who are in the programs that we provide support for find it a very helpful program with the kind of supports, because we provide a range of programs, and we've recently introduced medication-assisted treatment into those programs as well.

Mr. COLLINS. So are these women finding you on their own, or are their physicians guiding them to you?

Ms. HYDE. The women who come to our programs come from a variety of places; some from the correctional system, some from physicians, some from family, some from self-referral. So they come from a number of places, and we don't make a distinction between where they come from in terms of providing the care.

Mr. COLLINS. Well, it's something this committee's very concerned with. And, again, Mr. Chairman, thank you for holding this hearing and for all of your testimony. I wish there was an easy solution. There just doesn't appear to be one. So this is going to have to be addressed on a lot of fronts. And with that, I yield back.

Mr. MURPHY. Mr. Tonko, you're recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chairman. And let me join in welcoming the Conway family to the hearing, and let me compliment the Honorable Michael Botticelli for having the roots, origins in the 20th Congressional District of New York. So welcome all.

One of the biggest concerns I hear from individuals and families struggling with addiction is the difficulty they have accessing treatment. As you know, with the Mental Health Parity and Addiction Equity Act, as well as with our Affordable Care Act, millions more people have gained access to mental health and substance use services. However, recent reports have laid bare the fact that these new treatments as options sometimes exist on paper only.

So my question first to Assistant Secretary Frank, Dr. Frank, what is HHS planning to do to increase the public disclosure of the Medicaid management practices insurers use both on the commercial side and on Medicaid and CHIP so that consumers can truly evaluate their health plans to make sure they are in compliance with parity?

Dr. FRANK. Thank you for the question. We, too, view the Mental Health Parity Act as an incredibly important opportunity to increase the use of evidence-based practice and access to treatment.

We are doing a number of things. We work with both the Department of Labor on the ERISA side of the commercial health insurance side. We've trained the ERISA investigators in how to detect deviations from parity arrangements within insurance, and so they are out there fully trained now working on these issues. We have a group within HHS who regularly provides technical assistance to State insurance commissioners and works with them to resolve complaints as they arise. And we've continued a series of forums and technical assistance around the country. And we're working with stakeholders, some of whom are in this room today, to improve our ability to ask for disclosure and to offer up consumers the opportunity to really make that evaluation that you referred to.

Mr. TONKO. Thank you, Assistant Secretary.

And Director Botticelli, I would like to talk about another barrier to treatment for some patients. And press accounts have suggested that some States are denying patients access to drug courts if they are receiving medication-assisted treatments, or MATs. I understand this has been a problem in Kentucky, at least according to some press accounts. So, Director, can you explain what is going on here? Given the importance of MATs, why are some judges attempting to cut patients off of medicines that can actually help them recover?

Mr. BOTTICELLI. Thank you, Congressman. And as many of my colleagues have talked about today, increasing access to medication-assisted treatment along with other behavioral therapies is the best course of treatment for people with an opiate use disorder. Unfortunately, one of the access issues that we find in addition to issues around payment has been particularly lack of access within the criminal justice system, and we know that many people with opioid use disorders are ending up in our system.

Drug courts, some drug courts have not adapted policies that the National Association of Drug Court Professionals endorse in terms of ensuring that people who do have an opioid use disorder get ac-

cess to those medications, as well as not predicating their participation that they get off these medications.

Part of what we've been doing on the Federal level is using our Federal contracting standards to ensure that people with opioid use disorders, whether it's in a drug court or a treatment program or in other venues, are offered access to medication-assisted treatment and are not denied participation based on the fact that they are on physician-prescribed medication.

Mr. TONKO. Dr. Volkow, on that same issue, do you agree with the assessment?

Dr. VOLKOW. Yes, I agree very much. And at the same time, we are developing alternatives that may be more amenable for the criminal justice system, like prison or jail, like the naltrexone antagonist, so there is no reason why they should not get access to medication.

Mr. TONKO. OK. And another barrier that patients face is the lack of available treatment providers who can prescribe MATs. Director Botticelli, can you comment on this dearth of providers who can prescribe buprenorphine, for example, what are some of the reasons for the shortage and what can we do to address it?

Mr. BOTTICELLI. One of the other opportunities that we have is ensuring that all of our treatment programs either offer medication-assisted treatment or to refer to programs that have medication-assisted treatment. An analysis of our treatment programs show that a very low percentage of them have incorporated medication-assisted therapies into their programs. Some of this, Congressman, quite honestly, has been by myth and misunderstanding and this divide between abstinence-based care and medication-assisted treatment, which I think is really unfortunate that we have here, so we really want to make sure that if a client is entering a treatment program that has particularly Federal funding needs to offer, by way of its own offering or through referral, medication-assisted treatment.

Mr. TONKO. All right. Thank you very much. And thank you to the entire panel for guiding us in this crisis situation.

Mr. MURPHY. I just want to ask as a clarification for the question you were asking about the drug courts and the use of a medication-assisted treatment. So you're recommending medication-assisted treatment as part of an option package, although you say obviously we want to get people free from drugs all together, does it require a recommended practice from your agencies to get drug courts to do that? Does it require regulatory changes from one of your agencies to do that? Or does it require a legislative solution from us to do that?

Mr. BOTTICELLI. And other panelists could add—this is—we've actually been doing that as a condition of their Federal—

Mr. MURPHY. OK.

Mr. BOTTICELLI (continuing). Drug court language.

Mr. MURPHY. OK.

Mr. BOTTICELLI. You know, again, we want this to be decided by an expert in addiction services in consultation with the—

Mr. MURPHY. OK.

Mr. BOTTICELLI (continuing). But we just didn't want to have categorical denial.

Mr. MURPHY. Ms. Hyde, are you adding to that question?

Ms. HYDE. I did mention in consultation with ONDCP and also with the Department of Justice, we have changed the language in our request for applications for drug courts so that they can't require that someone either get off of or not be on medication-assisted treatment if it is prescribed appropriately by a physician or a certified program.

Ms. DEGETTE. So I just wanted to add, though, what you can do, you can make the Federal funding contingent on full programs, but we can't force the States or whatever regulatory agency is setting up the drug courts to offer this. They just can't get Federal money if they don't offer it.

Mr. BOTTICELLI. And this is where I'm glad the committee is actually going to be talking at State level, because as a former State administrator, States do play a crucial role. There are many, many programs out there that actually don't receive Federal funding, or drug courts that don't receive Federal funding. We hope that our policies and procedures are adopted by those nonfederally funded programs, but States play a key role in licensing treatment programs.

Mr. MURPHY. Thank you.

Mr. BOTTICELLI. And they, I think, can look at the opportunities of increasing or ensuring that State licensing treatment programs also have the same kind of language.

Mr. MURPHY. Thank you. Speaking of States, go to the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you very much, Mr. Chairman, and thank you again for these hearings that we've been having on this topic.

As an engineer, I need to see things in perspective, and so I guess we've been following this over the last 4 years in Congress, and especially on this committee, been trying to look at this issue, and I think at one of the last meetings we just had, I tried to put it in perspective by saying from—Botticelli, you said there were 44,000 overdose deaths. I want people to understand, that's more than died in Vietnam in combat. I don't know that the American public understands that. And every day on the news, NBC or whatever, they had body counts and they had that, and people were outraged over that.

I'm not getting the sense of outrage over every year we lose as many people to drug overdose as we did in a 10-year war in Vietnam. I'm concerned when I had affirmed that in West Virginia, one in five babies born in West Virginia, and I'm sure it may be one in four in other States or so, but one in five babies, they've been affected with drugs. I keep thinking this in perspective by saying in Europe, the overdose rate is approximately 21 per million; in America, it's seven to 10 times that amount.

Now, I get a little on the verge of outrage. You know, I'm the father of four and grandfather of six, and I see these are what we're giving our kids, this is what the future is. And I hear this testimony from this panel of seven and the seven before that and the seven before that, and quite frankly, I get confused, because I don't know what the priority is.

From the business community and you all here in Washington, everyone loves to plan, but they don't carry out. Now, that may be

insulting, and I don't mean it in an insulting fashion, but we still have 44,000 people who will die between now and next year because we don't have a prior—I'd like to think that we could come up with one plan, one way, if you had at least one, prioritize it, what's the one thing, and then let's put everything we have into it, that Manhattan-type project, go after that one solution and see if that doesn't start the ball rolling in the right way, and then we can do two, three and four with it, but a focus; but I don't see a focus. I didn't see a focus from you. I heard seven, eight different ways that we might be able to approach this problem, because the planning—everyone loves to plan, but the implementation falls short.

So, since you're meeting on a regular basis, couldn't you come up with one—one idea to where we ought to begin to where we can really—the metrics, we get the optics and everything, we can really dig into that, and then we can have plan B, C and D, but let's achieve one instead of continuing to melt down as we do at this. I don't want to see another statistic of 44,000 more people die of overdose.

So I hesitate to ask, can you come up with an idea today in the time frame, is there one, just one idea that we should focus on? What's the best way? Is that in the drug use, is that in real-time on purchasing the prescription drugs that it's a national database, is that the number one thing we should do? I mean, my God, the Federal Government just changed the sentencing guidelines for heroin and they said if you're caught with 50 hits of heroin, you get probation. What are we doing? Are we fighting heroin or not? I'm really frustrated with this, so I really—give me some more guidance on plan one.

Mr. BOTTICELLI. So, Congressman, I appreciate your attention to this. And, you know, myself and many of our colleagues have been doing this work for a long time and, I think, are filled with a sense of tragedy in terms of where we are, and know that we can do better and know that we can work with Congress.

You asked for one. I think there are three areas, and some of these are articulated in the Secretary's plan, that we've got to do. We've got to change prescribing patterns in this. We are prescribing way too much medication, and that's starting the trajectory. We need to increase our capacity to treat the disease so that people who go down that path have adequate access. And the third is that we really need to focus on reducing overdose deaths.

Those are three areas that I think we can work with Congress on to really look at how do we increase our efforts.

Dr. FRANK. Let me add on to that on behalf—it seems that people from West Virginia all sort of think alike that way. And our Secretary, who shares the same experience you do has pushed us to focus and to take action in those three areas. And, you know, with it—this year we more than quadrupled our funding in those areas, and we're going to triple that again if our plan goes through, and these are in those three focused areas, because that's where the evidence says we should be doubling down, and that's sort of what is guiding us.

Mr. MURPHY. Thank you. Is the Secretary asking for legislation on this, then, to facilitate the answer to that question?

Dr. FRANK. There are some legislative proposals, and some of it is just increasing some of the use of our discretionary funds, and we got some additional appropriations this year, and then in the President's budget, we have sort of some legislative proposals for—

Mr. MURPHY. Could you please let this committee know if there's enabling language we have, and that would help address Mr. McKinley's question?

Dr. FRANK. Yep.

Mr. MURPHY. Thank you.

Ms. Clarke of New York, you're recognized for 5 minutes.

Ms. CLARKE. I thank you very much, Mr. Chairman, and our ranking member, and thank you to all of our witnesses for giving the committee the benefit of your expertise and experience today.

I'd like to focus my questions on the prevention side of the equation, how do we prevent opioid addiction in the first place. So, Dr. Volkow, picking up actually on a point that Mr. Botticelli made just a moment ago about way too many prescriptions, this is to you: Why are so many prescriptions being written for opioids? Are physicians not getting the appropriate level of training and education in pain management for responsible opiate prescribing practices? What would you say?

Dr. VOLKOW. There are both. Actually, what had happened is we have to recognize that there's another epidemic, of chronic pain in our country, estimated at 100 million people, according to the Institute of Medicine. As a result of the pressure of needing to address this problem, the joint accreditation require that hospitals and physicians in hospitals ask questions about pain and treat them. This was in 2000. And the problem was that that was not associated with the education required in order to be able to properly screen pain, but also to manage it, and to manage it and use opioid medications adequately. So there was a big gap between the need to implement better treatment for pain, but an inadequate education of that system, so that is a major problem.

I think that in terms of prevention, we have to recognize two aspects of this epidemic that are different from the others. One of them, we do have individuals that start diverting and they get the medications because they want to get high, but then there's the other element that is as important, of individuals that are properly prescribed the medication because they have pain. And in the past, it was believed that if you got an opioid and you had pain, you would never become addicted. Now the data shows us that that's not correct. We don't exactly know what percentage of individuals that will be treated for their pain will become addicted. The range goes enormously from none to something like 40/60, so we have no real idea. And that's why I highlighted the notion of, we need to be very aggressive in the education of healthcare providers on the screening and management of pain, but also be very aggressive on the education of healthcare providers for the recognition of substance abuse disorder so that they can determine who's vulnerable, and when a person that's properly being treated is transitioning, and how to intervene.

Ms. CLARKE. Very well. Thank you very much.

Director Botticelli, does ONDCP believe that the Federal Government should mandate continuing medical education on responsible opioid prescribing practices as a precondition of DEA registration to prescribe controlled substances? And can you elaborate on how that would work if that's the case?

Mr. BOTTICELLI. Sure. We do support mandatory prescriber education. I think for all of the evidence that you've heard today, it's very clear that if we really want to prevent both prescription drug misuse and heroin use and overdoses, we need to stop prescribing these medications so liberally.

There was a recent GAO report that showed that physicians get little to no pain prescribing, and actually veterinarians get more pain prescribing than physicians in the United States. So we don't think that it's overly burdensome to require physicians in this epidemic to have education.

I think, as you talked about it, we'd have to work with the legislature to look at changes to the Controlled Substances Act to ensure that a certified continuing medical education program would be linked to the DEA licensure or relicensure process, and that we would oversee those courses that we believe have the core competencies that we think are important and monitor who takes those.

Ms. CLARKE. Very well. Thank you very much.

Dr. Throckmorton, manufacturers of opioid pain relievers are currently required to offer free voluntary education to physicians on responsible opioid prescribing practices. However, as I understand it, physician participation rates for these voluntary educational courses are fairly low. Is that correct?

Dr. THROCKMORTON. We do have those programs in place. They were put into place about 18 months ago, and so the initial year was spent putting into place a process to allow the education to be available, prescribers to make use of it. During that time, we saw about 20,000 prescribers that are using extended-release, long-acting opioids sign up for one course. That's true, 20,000 out of 320,000 prescribers that prescribe these medicines is not a large fraction. It is progress. What we hope is in the second year, which will end in July of this year, we'll see a larger increase in terms of uptake and use of this education. We have been working with the continuing education community to make better use of it, make it more available. We're optimistic. We hope that we'll see more use.

It's one of two pillars of education, from our perspective. Combined with the mandatory education that Mr. Botticelli just spoke about, we believe both of these things provide important opportunities to educate prescribers.

Ms. CLARKE. Very well. I yield back. Thank you very much.

Mr. MURPHY. Thank you.

Mrs. Brooks of Indiana, 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman, for continuing the focus on this critical subject for our country.

I want to start with you, Dr. Volkow. We talked about how the opioid addiction facing the country is, in large part, due to chronic pain. And you mentioned that 100 million people suffer from chron-

ic pain. I've heard up to one in three Americans actually possibly suffer from chronic pain.

And one of the goals of this hearing is to try to focus on evidence-based treatment and new treatments in trying to find out what it is that is working. And, obviously, one treatment doesn't work for everyone, as we've heard.

But I learned about, in the course of examining this, that there are some technologies that are new, not completely new, but one being—I was told about spinal cord stimulation, which targets nerves with electrical impulses rather than drugs, and that clinical studies have shown it to be safe: 4,000 patients have received this stimulator. And so it obviously is a device, a technology that can actually stop that stimulation and can help hopefully end that addiction, but yet NIH hasn't included that in its draft pain strategy. It didn't mention technologies like SCS.

Can you talk at all about why it wouldn't be promoting this FDA-approved type of technology? And are there other technologies we ought to be talking about other than medication for chronic pain?

Dr. VOLKOW. Yes. Thanks for the question.

And this is an area that is rapidly evolving. And if it's not mentioned, it's because many of the findings are way too recent. And the one that you're commenting on in terms of stimulation is one of the strategies in which we're also promoting research. And the same strategy can be utilized to be able to actually inhibit the emotional centers of the brain that react to pain.

So researchers are utilizing a wide variety of tools and technologies that have evolved as part of our initiative to understand the brain. That, again, highlights—but it brings up something that, I think, is facing us in this epidemic: the need that we have to develop better strategies for the management of chronic pain, because the physicians are forced—patients in great suffering, they don't know what to do, and they give an opioid even though the evidence does not really show us they are very effective for the management of chronic pain. But there are not many out there.

So recognizing that this is an area where we are required to invest resources for having alternatives for patients suffering from chronic pain is an extremely important part of an initiative of addressing the opioid epidemic.

Mrs. BROOKS. How would you recommend we increase, then, patient access and educate more physicians about this type of technology?

Dr. VOLKOW. Well, this is a new technology, some of them. Actually, the evidence is just emerging. It will have to be submitted to the FDA for approval. And then physicians, as part of their training, should be exposed to them. And I would say—I am just highlighting in the notion because Michael Botticelli very clearly delineated, I also think it's important that medical students, as part of their basic training, have an understanding of these technologies because pain is part of every medical condition, almost of every medical condition.

Mrs. BROOKS. Thank you very much.

I'd like to ask you, Mr. Botticelli, my State, State of Indiana, recently passed a law allowing physicians to prescribe the naloxone

to parents and to others and friends, giving them greater access to the reversal heroin drug.

Would you speak as to what's known about the impact of the naloxone programs and whether you have concerns about whether the naloxone might encourage actually more risk-taking? Because I met with law enforcement who said they had given naloxone, had saved their lives and, a couple weeks later, saved their life again with the naloxone. And so I am somewhat concerned—and I absolutely want to save lives, and we must. And we know there aren't enough treatments. This is obviously a huge problem.

But might that encourage an addict, if they knew their mom, dad, or friend had the save right there? Can you talk to us about these naloxone programs?

Mr. BOTTICELLI. Sure. So, to your first question, obviously, naloxone distribution by as many people who have the potential to witness an overdose is particularly important. And law enforcement, particularly in rural counties, also play a key role in that effort.

I will tell you, by way of—when I was in Massachusetts, we significantly increased access to naloxone and actually did a peer-reviewed study that showed when you introduced naloxone into a community, overdose rates go down. And the more naloxone you introduce, the better the scale effect.

You know, one of the pieces that we are concerned about—but there is absolutely no evidence to show that naloxone distribution actually increases drug use. Some of the issues that you mentioned become critically important, that overdoses are often seen as a significant motivator for people to seek care. But having treatment on demand is a particular issue. Treatment on demand, particularly in some of our rural communities, is particularly an issue.

Interventions that are emergency departments to get people into care become critically important. So while we know that addiction is a chronic disease, and some people do continue to use, when you have these adverse events, but we also need to know we have to have a comprehensive response, not just saving someone's life.

Mrs. BROOKS. Thank you. I completely agree, and I certainly hope the results in Indiana prove out to be the same as in your State.

And I yield back. Thank you.

Mr. MURPHY. Gentlelady yields back.

Mr. Mullin from Oklahoma, you're recognized for 5 minutes.

Mr. MULLIN. Thank you, Mr. Chairman.

Before I get to some questions, I have got a followup question for Ms. Hyde. The last time that you were in front of this committee, which I really appreciate you coming back, we had discussed your Web sites and if they were an effective use of taxpayer dollars. At that time, you stated that you were all in the process of evaluating that. Have you finished that process yet?

Ms. HYDE. That process continues. Thank you for asking the followup question. The process continues. I think the Web site that you indicated most concerns about was one of the Web sites that we were in the process of reviewing. It was originally developed based on data and knowledge from NIDA.

Mr. MULLIN. Right. And which—

Ms. HYDE. And we have—

Mr. MULLIN. Well, that was for the 3- to 6-year-old for suicide prevention. Have you finished that one yet?

Ms. HYDE. Yes. Building blocks—

Mr. MULLIN. Right.

Ms. HYDE (continuing). I think is the one you were concerned about. We have worked with our colleagues at NIDA and determined that the Web site hadn't been updated in a while, so it needed to be updated. So we have taken it down and are in the process of updating it.

Mr. MULLIN. Could you give me some process reports on that, just so I can kind of know where you guys are at? We just want to make sure that taxpayer dollars are being used in an effective way.

Ms. HYDE. Certainly.

Mr. MULLIN. To get to the questions, Dr. Throckmorton, just a simple yes or no. Does the FDA recommend that methadone be used as a first line of therapy for chronic pain?

Dr. THROCKMORTON. Methadone is approved for use for pain, yes.

Mr. MULLIN. But I am specifically speaking to the first line, for a first line of defense, basically.

Dr. THROCKMORTON. It's one of the medications that we have approved for pain. I will say, however, that if you look at methadone, if you look at the labeling that we have for methadone, it calls it out as far as a product that has particular characteristics that make it challenging to use for pain.

Mr. MULLIN. So that would be a no for the first line.

What is your recommendation for first line?

Dr. THROCKMORTON. Our recommendation is prescribers think very carefully before using methadone. There are things that make it a challenging product to use. It is approved for use in that setting, but I hope doctors think very carefully before they do it.

Mr. MULLIN. Well, the FDA put out a warning about the drug safety and basically said that you guys—that insurers should not—should not be referred as a preferred therapy, unless special instructions and education was put onto it. So I would take that as the FDA would, by this statement, that it'd be a no, that you wouldn't recommend it unless there's a lot of consideration taken.

Dr. THROCKMORTON. Personally, what I just said is where I would be.

Mr. MULLIN. OK.

Dr. THROCKMORTON. I need to look at the statement and get back with you about the specifics of it.

Mr. MULLIN. OK.

Dr. THROCKMORTON. But it is a drug that has a very long half life that is variable patient to patient. It has unique cardiac toxicities. There are other drugs that are useful for pain that don't have those characteristics and I—

Mr. MULLIN. Sure. All I'm really looking for is a yes or no because I'm really trying to get further on down the line for questions. I do appreciate you being here. And I like the last name; that's my sister's last name. And I got some beautiful—

Dr. THROCKMORTON. A very good last name.

Mr. MULLIN. I know. I've got three beautiful nieces. But the spelling usually gets messed up.

Dr. Houry, what about the CDC? Do you guys consider this methadone as being a first line of defense for pain?

Dr. HOURY. At CDC, we just focus really on the primary prevention and not as much of the care, so I would defer to the sister agencies on that.

Mr. MULLIN. Which would be?

Dr. HOURY. The panelists here. FDA.

Mr. MULLIN. Well, Dr. Throckmorton kind of gave his personal opinion. But the statement of FDA you heard about. So would you follow the statement, I'm assuming?

Dr. HOURY. I would follow his statement. I don't have a personal opinion on methadone for pain. It's not something I did in my prior practice.

Mr. MULLIN. OK. Dr. Conway—by the way, I'm always jealous when people have their family with them. I have got five wonderful kids. And if you ever want to see me cry, that's about the only thing that will make me cry. I miss them.

Mr. MURPHY. How are your kids doing?

Mr. MULLIN. Thanks. I appreciate that. I will take a deep breath and wipe the tear away.

Are you aware that methadone accounts for 30 percent of overdose deaths while only accounting for about 2 percent of the prescriptions that are prescribed for chronic pain?

Dr. CONWAY. I am aware that it's a higher percentage of deaths compared to prescriptions because of the long half-life and risks described.

Mr. MULLIN. Would you personally recommend it as a first line of defense for pain?

Dr. CONWAY. So I'm a practicing physician. I do not, as a practicing physician, typically use methadone as a first defense. However, I think it depends on the individual patient characteristics and would defer to the physician's judgment with that individual patient.

Mr. MULLIN. Well, according to the Pew research, they put out a deal that said methadone is available in low-cost generic form and is considered a preferred drug in many States by the Medicaid programs, despite FDA warnings about the drug safety and the statements by the American Academy of Pain Medicine that insurers should not be preferred this therapy unless it's especially educated and provided to the individual.

I just kind of wonder if—overall, I would think, we're considering it not being there. Why is this still listed as a first line with Medicaid, I mean, when we're seeing so many deaths? It almost makes you think, is the cost of a life not more valuable than the cost of a low drug?

Dr. CONWAY. So I'd make a few points. Statutorily, the Medicaid programs have the ability to set their preferred drug list. However, we have taken a couple of actions that I think to try to address this issue. One, working with SAMHSA, NIH, and others on this panel, we have put out an informational bulletin to the Medicaid programs talking about this issue and a complete array of pain, both on the medication side, the risks of methadone, and the other op-

tions and, also, importantly as others have said, the importance of both behavioral treatment and medication treatment.

I'd also call out, in our Medicaid Innovation Accelerator Program, the first area we're working on is substance abuse disorders. We have over 30 States involved, and they're taking a comprehensive approach to the Medicaid program to appropriate substance abuse treatment, including appropriate use of medications and also other therapies.

Mr. MULLIN. Dr. Conway, appreciate it.

Mr. Chairman, I yield back.

Mr. MURPHY. Mr. McKinley has a followup question. Then I have a followup question, too.

Mr. MCKINLEY. Thank you for the opportunity just to follow up because one of the questions or statistics I was giving you in talking about prospectors is the model or the situation that they're facing in Europe. What do we have there in Europe? The average is 21 per million. And I was just looking at—that's the average.

Italy is below that. Latvia, Netherlands, Belgium, Greece, France, Poland, Portugal, Bulgaria, the Czech Republic, Slovakia, Hungary, Turkey, Romania, all have less than that, significantly less. What are they doing right? What are they doing differently in Europe than we are in America? Are we learning anything from them?

Dr. VOLKOW. There is something that we're doing very differently. And, actually, you picked up exactly on the point. If you look at the United States, for some of the medications we may be consuming 95 percent of the total production in the world.

So the question is, Are we a Nation that is so much in pain that we require these massive amounts of opiate medications? Or is there something that we are doing in terms of their access to them that is inadequate?

And I want, again, to reiterate the notion that, yes, we are over-prescribing opiate medications, on the one hand. But, at the same time, which is not exclusionary, sometimes we are undertreating patients with pain. So we are in a situation that we have it bad in both ways. Overprescribing, making these drugs available, which then can be easily diverted, and prescribing them to those that don't need them can also result in adverse consequences. You don't see that level of prescriptions in any of the European countries.

Mr. MCKINLEY. So what's the—why not? What are they doing? Are their doctors more sensitive to this issue than our doctors in America? Are they concerned about the trial lawyers? What's the difference between it?

If there are 10 to 15 times more people dying in America than there are in Europe, something is wrong. They're doing something differently, and I'd like to know what it is.

Dr. VOLKOW. And that's exactly the way that I say we have to aggressively institute the education of the healthcare providers on the proper screening and management of pain—that's a crucial component—while also educating them about the adverse effects as it relates to substance abuse disorders.

And we need to face the fact that we need to also provide alternative treatments for the management of chronic pain that are effective.

Mr. MCKINLEY. OK.

Yield back.

Thank you very much for that.

Mr. MURPHY. Ms. Brooks, you have a quick question?

Mrs. BROOKS. Thank you. Actually, I realize Mr. Botticelli mentioned it in his opening, and I wanted to have an unrelated follow-up if I might, Mr. Chairman.

Mr. MURPHY. Yes, you may.

Mrs. BROOKS. You mentioned—and we are having a crisis in Indiana in Scott County, a community of 4,300 people, an outbreak of HIV due to needle exchange. And I would simply like—and I hope that many of you have been following what has been happening and the number of citizens in Indiana who now have contracted HIV because of their, in all likelihood, heroin addiction, right.

Mr. BOTTICELLI. Prescription drug.

Mrs. BROOKS. Or prescription drug addiction and possibly heroin addiction as well.

I am very curious, since I have this incredible panel of experts here, what you might say to our State and to the health professionals, our public health professionals who are dealing with this crisis, to our State and local government officials, what advice and thoughts do you have for our State? And I truly, if we could, this is a crisis in our State that I think could be in any State in the country.

Mr. Botticelli.

Mr. BOTTICELLI. Sure.

Mrs. BROOKS. And then anyone else who might comment, please.

Mr. BOTTICELLI. So, first of all, just about the staff from all of the agencies on this table coordinate on a daily basis in tight co-ordination with the Indiana Health Department to make sure that we are giving Scott County the resources they need to do that.

Mrs. BROOKS. Thank you. And I'm sure Dr. Adams appreciates that.

Mr. BOTTICELLI. You're absolutely right that while we're seeing huge—I think we're over 145 cases of HIV now—one of the consequences we've seen nationally is increases in viral hepatitis as it relates to sharing needles. And I think it also points to some issues that we need to include about access to treatment services.

So I think what's happening in Indiana in Scott County is emblematic of the potential that we could see in other parts of the country but points to some of the issues that we've been talking about today in terms of making sure that people have access to good care, both infectious disease care and substance abuse care; they have adequate access to clean syringes so that they are not increasing infection in this most poignant case of what we need; and that they're having timely access to treatment services, I think, are all areas to do that.

We'll continue to engage with folks in Scott County to make sure that whatever we can do on the Federal side can help alleviate the situation.

Dr. HOURY. And I'd just like to add to that I'm really proud of all of the efforts CDC is doing on the ground in Indiana and in conjunction with agencies here, I agree completely with Director Botticelli about the access to medication-assisted treatment as well as the HIV therapy.

The other thing I would add is Indiana is number nine in the Nation for prescribing, and so there's a lot that can be done when you're looking at, again, trying to stop the epidemic before it even happens. So looking at, again, using the Prescription Drug Monitoring Programs, having better prescribing guidelines, so that people don't get addicted to opioids, then inject them. So that's the third component, I think, we really need to add.

Mrs. BROOKS. Dr. Volkow—

Dr. VOLKOW. Yes.

Mrs. BROOKS. Or, I'm sorry, and Administrator Hyde. Maybe Dr. Volkow and then Administrator Hyde.

Dr. VOLKOW. I mean, we got caught by surprise with the Indiana epidemic of HIV, and I heard Tom Frieden say this is the fastest growing incidence of HIV cases that we've had since HIV entered the United States.

But there's been an extraordinary advance on HIV that has emerged really over the past 2 or 3 years, which is that if you initiate someone on antiretroviral therapy, not only are you going to be improving their outcome, but you are actually going to dramatically decrease their infectivity.

So, in looking forward—one of the things I would have suggested to do is once you start to see a case, you immediately treat them with antiretroviral therapy. They'll do better, and their infectivity will dramatically decrease. So this is another aspect, which actually relates to the issue of giving good infectious disease care to these individuals jointly with the interventions for substance abuse treatment.

Mrs. BROOKS. Thank you.

Ms. HYDE. So I just wanted to add that we are working collectively on this issue and that we understand there may be some legal barriers that we've been talking to Indiana about in terms of developing opioid treatment programs, and there's not a lot of waivered physicians able to provide buprenorphine. I think the closest opioid treatment program is about 40 miles away. There may be some transportation barriers and some cost barriers and other things. So we're collectively working with the State to try to help develop alternatives.

Mrs. BROOKS. Thank you, Mr. Chairman, for allowing me to give that voice.

Mr. MURPHY. Thank you.

I have two quick followup questions. First, Ms. Hyde, last week, the subcommittee heard testimony from Dr. Anna Lembke, the program director of the Stanford University Addiction Medicine Program that the 42 CFR part 2 is an artifact of the past. She told us the law's consent requirements are so stringent that two doctors seeking to treat the same patient for opioid addiction can't communicate with each other about the patient's medical condition. In fact, she cited that the subcommittee—and we received subcommittee reports. The rule was based upon a 1972 law, and it's

causing havoc in the age of electronic records. I guess sometimes the police would actually raid a methadone clinic and arrest people there.

So she has strongly recommend that we change that so we are not overprescribing people and a physician can know who is in treatment.

Now my understanding is that SAMHSA is contemplating new 42 CFR part 2 rules. And I just want to know if you're committed that these rules will reflect the concerns that have been repeatedly voiced by so many in the medical community who treat patients with substance abuse who want nothing more than to make sure patients aren't given double doses, so they can really communicate. Is that what SAMHSA is going to be working on?

Ms. HYDE. I really appreciate that question. It is a complex issue. And you're right; these laws and regs are decades old, before we had electronic health records, before we had collaborative care models and other things that we are now considering part of the practice.

We, a couple of years ago, put together some subregulatory guidance to try to help this issue, but that wasn't sufficient. So, last year, we held a listening session for stakeholders and have taken those pieces of input and are trying to balance the privacy concerns with the need for access to data. We hope that we will have something available for public input yet this year to try to address some of these issues.

Mr. MURPHY. And please let the committee know. Thank you.

And, Mr. Botticelli, I wanted to follow up on this Kentucky drug court issue. Could the drug courts' decisions relate to the issue of diversion? I mean, at a previous hearing, we heard testimony from witnesses that Suboxone mills are popping up in Kentucky and West Virginia and these are high problematic States. And, when entering the drug court system, it's nearly impossible to determine if the Suboxone is from an illicit source or prescribed by a doctor.

Could this be part of the issue and that the drug courts could really work and perhaps have some flexibility to deal with this on a case-by-case basis?

Mr. BOTTICELLI. So I think there are a number of issues. The National Association of Drug Court Professionals actually did a survey of drug courts in the United States. And for those drug courts that were not referring, it was actually more about judicial bias than it was about fear of diversion that kept people from doing that.

I think the second piece that any treatment, whether it's medication-assisted treatment or residential treatment, requires a level of collaboration and relationship between the court and the provider to ensure that courts who are referring to treatment are referring to high-quality treatment.

You know, we do need to pay attention to diversion. And drug courts, I think in combination with treatment programs, can ensure that these are appropriately prescribed and appropriately monitored medications. And they need to make sure that they're partnering with physicians who are implementing and dispensing medications in a high-quality way.

Mr. MURPHY. Now, part of this—I just got an article that was—I'm not sure what newspaper it is. But it was talking about in

some of these courts, they're using Vivitrol and for people in and out of incarceration trying to keep them off by maintaining Vivitrol.

So I just want to make sure I understand. They want to keep these people, after they're released from prison, drug-free. And so could you please clarify: Are you saying that unless they have some synthetic opiates, they're going to have Federal funding cut, or they can still maintain Federal funding and then Vivitrol would be acceptable as another part of the program?

Mr. BOTTICELLI. So we don't dictate to drug courts what medications. That actually should be a decision between the treatment provider and the patient.

I think our work here was just to make sure that there weren't categorical prohibitions for drug courts either to not offer medication-assisted therapies and, if someone was on a recommended course of treatment, that they not have to get off the medications to do that.

We actually don't dictate what medications courts use to be able to do that. I think, like any treatment, you want to have an arsenal of medications.

Mr. MURPHY. Dr. Frank, could you also respond to the Vivitrol question, too? Did you hear that? I'm just wondering as that as an option for States as a diversion to be using Vivitrol, that that could be part of what we could be—

Dr. FRANK. Well, I think that we are trying to have the full armamentarium available to the treating providers who are trying not to get between the provider and the patient as long as there is the opportunity to offer the richest menu of evidence-based treatments that are available.

Mr. MURPHY. Mr. DeGette, do you have a followup?

Ms. DEGETTE. Mr. Chairman, Mr. McKinley asked the witnesses what one thing would you recommend that we could do to try to start reversing this epidemic and this problem. He got as far as Dr. Frank when he ran out of time. So I just ask unanimous consent, if we can ask each one of the other witnesses—

Mr. MURPHY. Yes, please.

Ms. DEGETTE (continuing). To supplement their testimony. They don't have to say it right now.

Mr. MURPHY. Get back to us. Thank you.

Ms. DEGETTE. But if you can get back to us with that recommendation. We recognize there is a problem, and we are really struggling with the issue of what we do as a Congress to remedy it. Thank you.

Mr. MURPHY. And I think what you're also talking about, a partnership with the States—says we should be looking at Kentucky and some others—Indiana—

Mrs. BROOKS. Indiana.

Mr. MURPHY (continuing). Colorado, of course, and see what else is going on.

I want to thank this panel. We will follow up with the questions because we heard a number of recommendations from you, so we will ask for more clarifications of this.

Look, I want to thank you. As I said last time, too, you know, if this was about a single airplane crash, this room would be filled

with media. But we have had more people die in the last year from drug overdose deaths than the combination of every airplane crash in North America from 1975 to the present. And we have to make sure we keep this on the front page. This is a serious crisis and one, whether it's education of physicians, mandatory education, whether it's options out there, we want to make sure the evidence-based care and that Federal funding is going in the right direction.

So I'd like to thank all the witnesses and members that participated in today's hearing.

I remind members they have 10 business days to submit questions for the record, and I ask that all the witnesses agree to respond promptly to the questions.

With that, this committee is adjourned. Thank you.

[Whereupon, at 12:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 29, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing on "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?"

On Friday, May 1, 2015, at 9:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?" The purpose of this hearing is to confer with the relevant Federal agencies regarding their ongoing efforts to combat the opioid abuse epidemic and explore how Federal policies can most effectively incentivize the development and broaden use of evidence-based practices and treatments. Subcommittee members will hear testimony from senior officials representing the full range of multi-disciplinary activities comprising the Federal response to this epidemic.

WITNESSES

- Michael Botticelli, Director, Office of National Drug Control Policy, Executive Office of the President;
- Richard G. Frank, Ph.D., Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services;
- Nora D. Volkow, MD, Director, National Institute on Drug Abuse, National Institutes of Health;
- Douglas Throckmorton, M.D., Deputy Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration;
- Debra Houry, M.D., M.P.H., Director of the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention;
- The Honorable Pamela S. Hyde, Administrator, The Substance Abuse and Mental Health Services Administration; and
- Patrick Conway, M.D., M.Sc., Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer, Centers for Medicare & Medicaid Services.

BACKGROUND

This hearing follows up on the April 23, 2015, Subcommittee hearing on “Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives.” At that hearing, the Subcommittee heard from a panel of professional and academic witnesses that provided insights and findings, drawn from clinical practice and research—as well as constructive policy recommendations—from some of the nation’s foremost experts on opioid abuse. The Subcommittee heard testimony on treatment options currently available, as well as new and emerging evidence-based practices supporting individuals living with opioid abuse and addiction.

At the March 26, 2015 Subcommittee hearing on “Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives,” the Subcommittee heard from a panel of witnesses offering a “boots on the ground” perspective addressing the opioid abuse epidemic at the State and local levels, aiming to inform and improve the effectiveness of the Federal public health response to this nationwide problem.

Last year, on April 29, 2014, the Subcommittee held a hearing on “Examining the Growing Problems of Prescription Drug and Heroin Abuse.” At that hearing, the Subcommittee heard from a Federal panel of witnesses from the Office of National Drug Control Policy (ONDCP), the National Center for Injury Prevention and Control (CDC), the Office of Diversion Control (DEA), the National Institute on Drug Abuse (NIDA), and the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA).

Origins and breadth of the problem

The trends related to prescription drug misuse and overdoses involving opioids are alarming. Drug overdose death rates have increased five-fold since 1980.¹ From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics, or pain medications, nearly quadrupled.² By 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time. Abuse of opioid pain relievers claimed over 16,600 lives in 2010, resulting in over 400,000 emergency department visits in 2011, and cost health insurers an estimated \$72 billion annually in medical costs.³ Deaths related to heroin, an illicit opioid, also have increased sharply since 2010, including a 39 percent increase between 2012 and 2013.⁴ Mortality data show that there was a 6 percent increase in overall drug overdose deaths between 2012 and 2013

¹ M. Warner, et al, Drug poisoning deaths in the United States, 1980-2008, CDC National Center for Health Statistics data brief, no. 81 (CDC National Center for Health Statistics 2011).

² Centers for Disease Control and Prevention. QuickStats: Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics – United States, 1999-2013. MMWR Weekly. Retrieved from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm>.

³ CDC FY 2015 Budget Justification at 9.

⁴ Hedegaard H, Chen LH, Warner M.; National Center for Health Statistics (NCHS). Drug-poisoning deaths involving heroin: States, 2000-2013. NCHS data brief, no190. Retrieved from: <http://www.cdc.gov/nchs/data/databriefs/db190.pdf>.

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and approximately 37 percent of those deaths involved prescription opioids.⁵ The mortality rate from heroin overdose increased each year from 2010 to 2013.⁶ Deaths due to heroin overdoses increased by 39 percent from 2012 to 2013 alone and constituted as much as 19 percent of all drug overdose deaths in 2013.⁷ Heroin and prescription opioid abuse also can result in other health consequences, such as neonatal abstinence syndrome, increased risk of transmission of HIV and Hepatitis C, and bone fractures in older adults due to falls.⁸ On average, heroin addicts lose about 18 years of life expectancy, and the mortality rate for injection users is roughly 2 percent per year.⁹

Although heroin use in the general population is low, the number of people beginning to use heroin has been steadily rising since 2007. According to NIDA, this may be due in part to a shift from the abuse of prescription pain relievers to heroin as a more potent, readily available, and cheaper alternative to prescription opioids.¹⁰ In fact, nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.¹¹ Among those who began abusing opioids in the 2000s, 75 percent of individuals indicated they initiated their abuse with prescription opioids.¹² Although the available literature indicates that abuse of prescription opioids is a risk factor for future heroin use, only a small fraction, roughly 4 percent of opioid abusers, transition to heroin use within five years of initiating opioid abuse.¹³

⁵ Centers for Disease Control and Prevention. Wide Ranging Online Data for Epidemiologic Research (CDC WONDER). Available at: <http://wonder.cdc.gov/>.

⁶ *Id.*

⁷ *Id.*

⁸ Creanga AA, SabelJC, Ko JY, Wasserman CR, Shapiro-Mendoza CK, Taylor P, Barfield W, et al. Maternal drug use and its effect on neonates: a population-based study in Washington State. *Obstet Gynecol.* 2012; 199(5):924-933.; Zibell JE, Hart-Mallory R, Barry J, Fan L, Flanigan C. Risk Factors for HCV infection among young adults in rural New York who inject prescription opioid analgesics. *Am J Public Health.* 2014 Nov;104(11):2226-32. Doi: 10.2105/AJPH.2014.302142. Epub 2014 Sep 11.; Mateu-Gelabert P1, Guarino H2, Jessel L2, Teper A2. Injection and sexual HIV/HCV risk behaviors associated with nonmedical use of prescription opioids among young adults in New York City. *J Subst Abuse Treat.* 2015 Jan;48(1):13-20. Doi: 10.1016/j.jsat.2014.07.002. Epub 2014 Jul 11.; Rolita L, Spegman A, Tang X, Cronstein BN. Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. *J Am Geriatr Soc.* 2013;61(3):335-340.; Miller M, Sturmer T, Azrael D, Levin R, Solomon DH. Opioid analgesics and the risk of fractures in older adults with arthritis. *J Am Geriatr Soc.* 2011;59(3):430-438.

⁹ B. Smyth, et al., Years of potential life lost among heroin addicts 33 years after treatment, *44 Preventive Medicine* 369 (2007).

¹⁰ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821-6.

¹¹ NIDA Report Series, "Heroin," NIH publication number 15-0165, 3 (November 2014, rev.). Some data have higher estimates. Data from SAMHSA shows that 81 percent of people who started using heroin from 2008 to 2010 had previously abused prescription drugs. Amy Pavuk, *Rx for Danger: Oxycodone crackdown drives addicts to other drugs*, Orlando Sentinel, July 28, 2012, http://articles.orlandosentinel.com/2012-07-28/health/os-oxycodone-drug-shift-dilaudid-20120728_1_oxycodone-prescription-drugs-dilaudid-pills.

¹² Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry* 2014;71:821-6.

¹³ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. August 2013. Retrieved from: <http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf>.

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Overprescribing of painkillers has been a significant driver of our present opioid and heroin epidemic. Since 1997, the number of Americans seeking treatment for addiction to painkillers has increased by 900 percent.¹⁴ The prevalence of opioid addiction started rising as long-term prescribing of opioids for chronic pain, a practice encouraged by opioid manufacturers, became more common.¹⁵ As a result, many States started to make extensive use of their prescription drug monitoring programs as a tool to monitor prescription sales of controlled substances.¹⁶

Paths to recovery

There is a wide consensus among experts that medical best practice demands a full menu of behavioral, pharmacological, and psychosocial treatments be made available to individuals with opioid addiction. This is especially critical, as the Center for Addiction and Substance Abuse at Columbia University, in a five-year study, found that only 1 in 10 people with alcohol or drug addiction other than nicotine receive any form of treatment, and of those, only 10 percent receive evidence-based treatment.¹⁷ Nearly 80 percent of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.¹⁸ Many counties lack substance abuse treatment facilities that accept Medicaid.¹⁹ A 2007 SAMHSA analysis of workforce issues noted that more than 50 percent of U.S. counties in rural areas lack practicing psychiatrists, psychologists, or social workers.²⁰

In particular, the data suggests that medication-assisted treatment (MAT) is effective in treating opioid addiction and reducing overdose deaths. As drug abuse changes the way the brain works, resulting in compulsive behavior focused on drug seeking and use, medications can be helpful in treating the symptoms of withdrawal during detoxification – which often prompt relapse – as well as become part of an ongoing treatment plan.²¹ Scientific research has established that MAT increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.²²

At present, the Food and Drug Administration (FDA) has approved only three medications for the treatment of opioid dependence. Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid addiction for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both Federal and State

¹⁴ Science Daily, "Opioid and heroin crisis triggered by doctors overprescribing painkillers," Brandeis University, February 4, 2015, <http://www.sciencedaily.com/releases/2015/02/150204125945.htm>.

¹⁵ *Id.*

¹⁶ Ileana Arias, et al., Prescription Drug Overdose: State Health Agencies Respond, Association of State and Territorial Health Officials, 2008, http://www.astho.org/Programs/Prevention/Injury-and-Violence-Prevention/_Materials/Prescription-Drug-Overdose/.

¹⁷ <http://www.casacolumbia.org/addiction-research/reports/addiction-medicine>.

¹⁸ C.L. Arfken, et al, Expanding treatment capacity for opioid dependence with buprenorphine: National surveys of physicians, 39 Journal of Substance Abuse Treatment 96 (2010).

¹⁹ SAMHSA Budget Justification FY2016 at 5.

²⁰ *Id.*

²¹ NIDA Topics in Brief. Medication-Assisted Treatment for Opioid Addiction. April 2012.

https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf.

²² *Id.*

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regulation.²³ Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid addiction.²⁴ Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol.²⁵

Notably, the Department of Health and Human Services (HHS) includes expansion of MAT to reduce opioid use disorders and overdose among Secretary Burwell’s top three priority areas to combat opioid abuse, announced on March 26, 2015.²⁶ While MAT is a critical component of opioid addiction treatment, concerns have been raised that substance use disorders, as chronic conditions like diabetes or heart disease, demand a treatment model where long-term, sustained recovery – including extended engagement following formal periods of treatment – takes the place of what is too often the episodic, largely unsupervised prescription of medication followed by relapse to old habits.²⁷

With the aim of recovery in mind, long-term monitoring, both during and after episodes of MAT, is necessary to screen for the concurrent use of alcohol, illicit drugs, or the non-medical use of other prescription opioids that readily interfere with evidence-based treatments.²⁸ Dr. Robert DuPont, the first Director of NIDA, President of the Institute for Behavioral Health, and a witness at the April 23rd hearing has argued that widespread acceptance of “harm reduction” as the ultimate goal of MAT, has often undermined efforts to frame recovery, as opposed to relapse – or simply maintenance – as the expected outcome of addiction treatment.²⁹

At the March 26, 2015 hearing, the Subcommittee received testimony on the need for greater oversight of MAT and the need for standards on how these programs should be run. Professor Sarah Melton of East Tennessee University testified that “in Tennessee and southwest Virginia some buprenorphine programs have become pill mills where the physicians charge them high prices, they come in and get their medication, and they leave.” She also confirmed the “devastating” trend of medication-assisted programs providing methadone or buprenorphine in cash transactions and being incentivized to become pill mills. She also testified that there is a “dearth of access to good treatment, and by ‘good treatment,’ I mean patients being seen frequently, getting urine drug screens at nearly every visit, if not every visit, requiring 12-step

²³ The American Society of Addiction Medicine. Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.pdf.

²⁴ *Id.*

²⁵ *Id.*

²⁶ HHS Office of Assistant Secretary for Planning and Evaluation. Issue Brief, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. March 26, 2015. http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf.

²⁷ McGovern, John P. Institute for Behavior and Health, Inc. The New Paradigm for Recovery: Making Recovery – and not Relapse – the Expected Outcome of Addiction Treatment. March 2014. <http://ibhinc.org/pdfs/NewParadigmforRecoveryReportMarch2014.pdf>.

²⁸ *Id.*

²⁹ L. Merlo, M. Campbell, G. Skipper, C. Shea, and R. DuPont, “Recovery from Opioid Dependence: Lessons from the Treatment of Opioid-Dependent Physicians,” (Study supported by the Robert Wood Johnson Foundation, submitted for publication and currently under review) (2015).

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programs, group counseling, and not co-prescribing with other drugs of addiction such as benzodiazepines.”

Other issues

Use of methadone for pain. In addition to the overprescribing of prescription painkillers, public health risks have worsened by the increased prescribing of methadone for pain (as opposed to use in addiction treatment). The use of methadone as a treatment for pain has expanded in recent years. Although methadone can treat pain effectively, it carries outsized risks due to its unique pharmacologic properties, such as a long half-life, short analgesic window relative to respiratory-depressant effect, and potential for drug-drug interactions.³⁰ While methadone from methadone clinics is in liquid form, which addicts drink on-site, methadone prescribed for pain is in pill form, making it easier to divert and misuse. In contrast to the regulation of methadone clinics, no special licensing or monitoring is required to prescribe methadone in pill form. Methadone accounts for two percent of opioid prescriptions for pain control, but is responsible for one-third of overdose deaths, according to a 2012 CDC Vital Signs report.³¹ Most State Medicaid programs encourage the prescribing of methadone as a first line treatment for pain, often due to its low cost, even though safer therapies are available.³² Moreover, the FDA, the CDC, the American Academy of Pain Medicine, and the American Society of Interventional Pain Physicians have recommended that methadone not be used as a first-line therapy for chronic pain.³³

Prescription Drug Monitoring Programs. Prescription drug monitoring programs (PDMPs) are State-run electronic databases of prescriptions for controlled substances. PDMPs can provide a prescriber or pharmacist with information regarding a patient’s prescription history, allowing prescribers to identify patients who potentially are abusing medications. Currently, 49 States, the District of Columbia, and Guam have legislation authorizing the creation and operation of a PDMP, and all but the D.C. program are operational.³⁴ While there is evidence indicating the potential of PDMPs to identify high-risk patients and impact prescribing behaviors, the effectiveness of PDMPs is constrained by the lack of timely data in some States and limited interoperability with other PDMPs. Witnesses at the March 26, 2015 Subcommittee hearing also testified about their concerns over methadone clinics not being required to report methadone dispensing to PDMPs. One witness said it was “a very serious situation” because if these patients do not disclose their methadone treatment to their primary care providers and the providers do not know about it from accessing the PDMP, other opioids or benzodiazepines could be prescribed leading to death.³⁵ Another concern related to neonatal doctors not knowing

³⁰ The Pew Charitable Trust, “Prescription Drug Abuse Epidemic: Spotlight on Methadone,” August 2014.

³¹ <http://www.cdc.gov/vitalsigns/MethadoneOverdoses/>.

³² The Pew Charitable Trusts’ Prescription Drug Abuse Project, Undated handout (provided to committee staff, March 20, 2015).

³³ American Society of Interventional Pain Physicians, Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance, 15 Pain Physician Journal S67 (2012), <http://www.painphysicianjournal.com/2012/july/2012:S67-116.pdf>.

³⁴ PDMP Training and Technical Assistance center, PDMP Frequently Asked Questions, <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>.

³⁵ Testimony of Fred Wells Brason II, Executive Director, Project Lazarus, Moravian Falls, North Carolina. (Unofficial hearing transcript, 40).

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about methadone treatment for pregnant women who are drug-addicted, which poses potential problems for the mother and the life of the fetus if the methadone is being increased while the mother and baby are receiving opioid medication to treat the addiction.³⁶

Federal Agencies

- **Office of National Drug Control Policy:** The Office was established by the Anti-Drug Abuse Act of 1988. ONDCP is responsible for developing a national drug control policy, developing and applying specific goals and performance measurements to evaluate the effectiveness of national drug control policy and programs, overseeing and coordinating the implementation of the national drug control policy and assessing and certifying the adequacy of the budget for National Drug Control Programs.
- **Assistant Secretary for Planning and Evaluation (HHS):** The Assistant Secretary for Planning and Evaluation (ASPE), who advises the Secretary of HHS on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy, is spearheading recent HHS efforts to address the opioid abuse problem.

On March 26, 2015, HHS Secretary Sylvia Burwell announced a targeted initiative aimed at reducing prescription opioid and heroin related overdose, death, and dependence. The President's Fiscal Year (FY 2016) budget includes expenditures to intensify efforts to reduce opioid misuse and abuse, including \$133 million in new funding to address this issue. The Secretary's initiative targets three priority areas to combat opioid abuse:

(1) Helping health professionals make informed prescribing decisions –

- Teaching medical professionals how and when to prescribe opioids by working with lawmakers on bipartisan legislation requiring specific training for safe opioid prescribing and establishing new opioid prescribing guidelines for chronic pain.
- Supporting data sharing for safe prescribing by facilitating PDMP and health information technology integration and further adoption of electronic prescribing practices.
- Increasing investments in State-level prevention interventions, including PDMPs, to track opioid prescribing and support appropriate pain management.

(2) Increasing use of naloxone –

- Supporting the development, review, and approval of new naloxone products and delivery options.
- Promoting State use of Substance Abuse Block Grants funds to purchase naloxone.
- Implementing the Prescription Drug Overdose grants program for States to purchase naloxone and train first responders on its use.

3) Expanding use of Medication-assisted Treatment (MAT) –

³⁶ See testimony of Stefan R. Maxwell, MD, Chair, West Virginia Perinatal Partnership, MEDNAX Medical Group, Director NICU, Charleston Area Medical Center, Charleston, West Virginia. (Unofficial hearing transcript, 90).

- Launching a grant program in FY 2015 to improve access to MAT services through education, training, and purchase of MAT medications for treatment of prescription opioid and heroin addiction.
- Exploring bipartisan policy changes to increase use of buprenorphine and develop the training to assist prescribing.³⁷
- **National Institute on Drug Abuse:** The Institute, a part of the National Institutes of Health (NIH), supports research to prevent and treat drug abuse and addiction and mitigate their impacts. NIDA's efforts include identifying the characteristics and patterns of drug abuse and developing more effective strategies to prevent people from abusing drugs and from progressing to addiction. Their work also includes developing successful treatments for drug abuse and addiction and improving treatment accessibility and implementation.
- **Center for Drug Evaluation and Research (FDA):** Under the Food Drug and Cosmetic Act, the FDA is responsible for the approval and marketing of drugs for medical use and for monitoring products for continued safety after they are in use, including controlled substances used to treat pain. FDA is committed to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely manner and monitoring products for continued safety after they are in use. FDA aims to ensure that patients who require opioids for legitimate, medical pain control purposes maintain appropriate access to them through informed providers, while limiting misuse, abuse, and diversion of these products.³⁸
- **National Center for Injury Prevention and Control (CDC):** The National Center, a center within the CDC, researches ways to enhance State prescription drug monitoring programs, which track prescriptions for controlled substances, such as prescription painkillers. It also tracks and evaluates State policies and programs, like those to prevent "doctor shopping" and "pill mills" involved in painkiller misuse and overdose, while ensuring access to safe and effective pain treatment for those who need it. Additionally, the Center works to ensure that health care providers follow science-based guidelines for safe and effective prescribing of painkillers. Identifying health care providers who prescribe painkillers inappropriately could reduce overdoses and misuse, as the increase in overdose deaths parallels a sharp rise in the sale of prescription painkillers. Building off the infrastructure of the Prevention Boost and Core Violence and Injury Prevention programs, CDC received \$20 million in FY 2015 and will launch the Prescription Drug Overdose Prevention for States program, which fund expansion of State-level interventions including enhancements to PDMPs.³⁹ Another \$65 million is proposed in the FY 2016 budget to expand the program to all 50 States and Washington, D.C.⁴⁰ The PDMP component of this program is designed to advance broad adoption of universal, real-time, actively managed PDMPs.

³⁷ HHS Press Release, HHS takes strong steps to address opioid-drug related overdoses and deaths, March 26, 2015.

³⁸ Statement of Robert J. Meyer, M.D., FDA's Role in Preventing Prescription Drug Abuse

<http://www.fda.gov/NewsEvents/Testimony/ucm112718.htm>.

³⁹ HHS ASPE Issue Brief, note 26 at 6 (March 26, 2015).

⁴⁰ *Id.*

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- **SAMHSA:** SAMHSA's mission is to reduce the impact of substance abuse on America's communities. With respect to opioid abuse, SAMHSA spent more than \$8.7 million on opioid treatment programs and regulatory activities in FY 2014. SAMHSA's Budget Request for FY 2016 proposes a total of \$25 million of spending for MAT, including a \$12 million request for a new community-based program to prevent prescription drug and opioid overdose-related deaths and proposed increased funding of \$13 million for medication assisted treatment. The new community-based program will provide grants to 10 States to reduce significantly the number of opioid overdose-related deaths. Funding will help States purchase naloxone, equip first responders in high-risk communities, support education on the use of naloxone, and other overdose death prevention strategies. The MAT program request would increase the number of States from 11 to 22 that receive funding to expand services that address prescription drug misuse and heroin use in high-risk communities. The new funding is expected to serve an additional 24 high-risk communities. The FY 2016 budget also requests \$118.3 million, an increase of \$8.8 million from FY 2015 enacted level, for the Strategic Prevention Framework (SPF-Rx) program. The aim of SPF-Rx is to raise public awareness about the dangers of sharing medications and to work with pharmaceutical and medical communities to raise awareness on the risks of overprescribing.
- **Centers for Medicare & Medicaid Services:** The Centers for Medicare and Medicaid Services are responsible for administering the Medicare Part D drug program, and the Medicaid program, which significantly impacts the opioid epidemic program through coverage and funding of beneficiaries and providers. In 2014, CMS committed to take the problem seriously and begin actions to protect Medicare beneficiaries and the Medicare Trust Fund against Part D fraud and abuse.⁴¹ CMS is targeting Part D enrollees who use opioids to see if they have overutilization issues and physicians who may overprescribe. CMS focuses its fraud and abuse strategy on the validation and analysis of Part D claims data it receives from Part D sponsors. With regard to Medicaid, the 2013 study by the American Society of Addiction Medicine (ASAM) found that Medicaid coverage of, and patient and practitioner access to, opioid dependence treatment medications demonstrated important coverage and use limitations.⁴² Critically needed medications that could reduce the opioid overdose epidemic were substantially underutilized by State Medicaid programs. Moreover, ASAM practitioners reported Medicaid coverage, utilization management, financing, reimbursement, and regulatory issues as significant obstacles. A witness testifying at last week's hearing⁴³ and the Senate Caucus on International Narcotics Control⁴⁴ have raised questions over whether CMS quality measures may contribute to the overprescribing of opioid medications.

⁴¹ CMS Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse (January 6, 2014), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-01-06-2.html>.

⁴² S. Rinaldo and D. Rinaldo, The Avisa Group, "Availability Without Accessibility? State Medicaid Coverage and Authorization Requirements For Opioid Dependence Medications," report prepared for the American Society of Addiction Medicine (June 2013).

⁴³ Written testimony of Anna Lembke, M.D., before the House Energy and Commerce Subcommittee on Oversight and Investigations, Hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives," April 23, 2015.

⁴⁴ June 23, 2014 letter from the Senate Caucus on International Narcotics Control (Co-chairmen Senator Charles E. Grassley and Senator Dianne Feinstein) to The Honorable Marilyn Tavenner, Administrator, CMS.

ISSUES

The following issues may be examined at the hearing:

- What Federal programs have been effective in combatting opioid abuse and why?
- What Federal programs have not been effective in combatting opioid abuse and why?
- Are Federal health programs combatting opioid abuse adequately coordinated?
- Are Federal agencies collecting and evaluating the best data to determine the effectiveness of medication-assisted treatment programs?
- How can Federal policy better support efforts to develop new and promising treatments for opioid addiction?
- What are the best practices for treating opioid addiction, and how can Federal policy better incentivize these practices?

In addition, the following policy ideas or areas were mentioned in last week's Subcommittee hearing and could be raised for further exploration with the witnesses:

1. Changes to 42 CFR privacy regulations may be needed to update standards for integrating physical and behavioral medicine.
2. Addiction-treatment physicians should have all available tools "in their quiver" of treatment options, including the array of FDA-approved medications to treat opioid dependency.
3. Patients and sponsoring family members must be given more information regarding the probability of success for various treatment approaches. This will allow them to seek informed choices on which treatment approaches to consider.
4. Improve communication between pharmacies and physicians.
5. Define recovery – not in terms of today, but longer term – 5 years – so we see addiction as a chronic disease and see treatments as meeting chronic care.
6. Ensure physicians treating patients with pain have sufficient information and resources.
7. Make sure insurance parity is being enforced and that insurance companies are not arbitrarily discontinuing coverage for treatment at a certain time.

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8. Increase the number of providers who are trained and experienced for mental illness, serious mental illness, and addiction.
9. Increase the number of in-patient beds for detoxification and in-depth treatment that meets the needs of patients.
10. Increase the number of physicians that can prescribe MAT in regions of the country where opioid abuse/dependency is high and where medical services are sparse.
11. MAT alone or psychotherapy alone are rarely sufficient; make sure patient needs are met with all available treatment.
12. Ensuring drug courts allow treatment with MAT.
13. Combining the funding for mental health and substance abuse for dual diagnosis
14. Stop State Medicaid plan reimbursement policies from incentivizing the prescribing of methadone as first-line therapy for pain.
15. Making naloxone (narcan) available over-the-counter.

STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Sam Spector, or Brittany Havens of the Committee staff at (202) 225-2927.

Physician-Issued Opioids Associated With Higher ED Use

Alicia Ault April 30, 2015

Users of prescription opioids for nonmedical reasons make more visits to the emergency department (ED) than people with problems with alcohol or marijuana, a nationally representative survey has shown.

And getting those opioids from physicians is a leading independent predictor of emergency department use in the previous year, according to Joseph Frank, MD, from the VA Eastern Colorado Healthcare System in Denver.

As a practicing primary care physician, Dr Frank says he frequently deals with the challenges and complications of treating pain with and without opioids. Physicians "are increasingly being asked to pay extra attention to how we're using these medications," he explained.

"Our study adds to the evidence of the size and scope of the problem of nonmedical use of prescription pain medications," he told *Medscape Medical News*.

He presented the findings at the Society of General Internal Medicine 2015 Annual Meeting in Toronto.

Dr Frank and colleagues conducted a serial cross-sectional analysis of data from the National Survey on Drug Use and Health from 2008 to 2013. They assessed the nonmedical use of opioids and the implications of that use in a nationally representative sample of 228,556 noninstitutionalized respondents 18 years and older in the United States.

Survey respondents were asked whether they had used a prescription opioid pain medication "that was not prescribed for you, or that you took only for the experience or feeling it caused."

On the basis of the self-reported responses, Dr Frank's team estimated that, for each of the survey years, 10.5 million (4.6%) adults used opioids for nonmedical reasons. Of those, 840,000 (8.0%) reported nonmedical use on at least 200 days in the previous year.

Tip of the Iceberg

"Given the stigma associated with substance use, there may be under-reporting, which would mean that our estimate of 10.5 million adults with previous-year nonmedical use is an underestimate," Dr Frank told *Medscape Medical News*.

Respondents who reported previous-year nonmedical use were young (60% were younger than 35), and more likely to be male, white, and uninsured, he reported. The primary source of opioids was cited as one or more physicians by 20% of users. In addition, 14% of users reported experiencing opioid withdrawal symptoms in the previous year.

More adults with previous-year opioid use than adults in the general population visited the emergency department in the previous 12 months (39% vs 27%; $P < .001$). In fact, previous-year opioid users accounted for 9.4 million emergency department visits annually, which is 7.3% of all annual visits.

On multivariable logistic regression analysis, there was a significant association between previous-year emergency department visits and previous-year opioid use (odds ratio [OR], 1.37; 95% confidence interval [CI], 1.30 - 1.44).

In contrast, there was no association between emergency department visits and alcohol-use disorders (OR, 1.07) or marijuana-use disorders (OR, 1.07).

Predictors of previous-year emergency department visits were at least 200 days of opioid use a year, compared with fewer than 30 days (OR, 1.43; 95% CI, 1.17 - 1.76), withdrawal symptoms (OR, 1.67; 95% CI, 1.44 - 1.95), and having a physician as source (OR, 1.87; 95% CI, 1.60 - 2.19).

Why More ED Use?

Opioid users might be more likely to visit the emergency department than alcohol and marijuana users because they could be seeking treatment for withdrawal symptoms or trying to obtain medications, "which is a unique aspect of this challenge that does not apply to marijuana and alcohol," Dr Frank explained.

Opioid users might also be more likely to experience an overdose.

And users receiving opioids from one or more physician might be "more likely to use them in riskier ways that lead to complications and emergency department visits," he said.

These findings are not surprising, said Andrew Kolodny, MD, chief medical officer of Phoenix House, a national nonprofit addiction treatment agency, and director of Physicians for Responsible Opioid Prescribing.

People taking opioids for at least 200 days a year are "likely to be addicted," he told *Medscape Medical News*, so it makes sense that they'd be showing up frequently in emergency departments.

Withdrawal can bring on severe anxiety, akin to a panic attack, so users will be desperate, Dr Kolodny explained.

One of the limitations of the study is that it does not include information on whether nonmedical use includes people who take a medication that was not prescribed to them to treat pain, said Dr Frank.

Dr Kolodny said he agrees. This is "an excellent survey for drug-use trends, but it's not good for telling us who among those drug users suffers from addiction," he said.

It is "very concerning" that physicians are a source for nonmedical users. This study "could lend support to those advocating for mandatory use of a prescription drug monitoring program," he added.

"A Teachable Moment"

This is a complicated problem that will require that we work together across specialties, across healthcare systems, and across state lines.

If a person is coming to the emergency department to get pills, "they're not coming in seeking addiction treatment," Dr Kolodny said. However, if they are there because of an overdose, "that's a teachable moment."

"It does look like policymakers and medical societies are beginning to pay attention, so there is some reason to be hopeful," he told *Medscape Medical News*.

"I think a constructive dialog is already happening among healthcare professionals, who are very aware of the urgency of this problem," said Dr Frank.

"We must continue to support research to understand how and why so many adults are using prescription pain medications nonmedically," he added.

Dr Frank said he will use the findings from this study to inform his practice, including screening for nonmedical use of opioids, and to try to understand withdrawal and how it drives healthcare use.

"This is a complicated problem that will require that we work together across specialties, across healthcare systems, and across state lines," he said.

Dr Frank and Dr Kolodny have disclosed no relevant financial relationships.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-2841

May 21, 2015

The Honorable Michael Botticelli
Director
Office of National Drug Control Policy
750 17th Street, N.W.
Washington, D.C. 20503

Dear Director Botticelli:

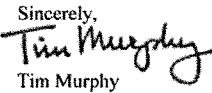
Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Thursday, June 4, 2015. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

 Tim Murphy
 Chairman
 Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
MICHAEL P. BOTTICELLI
DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING MAY 1, 2015, HEARING ENTITLED,
"WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT
THE OPIOID ABUSE EPIDEMIC?"
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Marsha Blackburn

1. ONDCP's plan recognized that "as a Nation, we must take urgent action to ensure the appropriate balance between the benefits prescription medications offer in improving lives and the risks they pose. No one agency, system, or profession is solely responsible for this undertaking. We must address this issue as partners in public health and public safety."

With all this in mind, does ONDCP support the goals of the "Assuring Patient Access and Effective Drug Enforcement Act," H.R. 471, which would require all affected stakeholders to work together to develop solutions in a collaborative manner to combat prescription drug abuse while also making sure that legitimate patients can still access their critical pain medications?

ANSWER:

It is important that any measure to address the prescription opioid epidemic addresses the public health consequences of the epidemic while ensuring that the tools available to law enforcement to address the public safety aspects of illicit drug use are not compromised. We do note that the House-passed version of H.R. 471 removes the Office of National Drug Control Policy (ONDCP) as a partner in the report to Congress on the effects of law enforcement activities on patient access to medications. We believe that ONDCP would have important contributions in the collaborative development of materials that address this subject, as you have suggested in your statements in regard to this bill.¹

Nonmedical prescription pain medicine use is more common than use of any category of illicit drug in the United States except for marijuana. In 2013, over 4.5 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.² In 2011 alone, 1.2 million emergency department (ED) visits involved the non-medical use of

¹ Blackburn Leads Effort to Combat Prescription Drug Abuse, Press Release, April 21, 2015. Available: <http://blackburn.house.gov/news/documentsingle.aspx?DocumentID=397716>

² Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: [http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7pcTabs1to45-2013.htm#\(tab7_3b](http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7pcTabs1to45-2013.htm#(tab7_3b)

pharmaceuticals.³ Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class, accounting for approximately 488,000 visits. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just 7 years earlier in 2004 (173,000). Opioid pain relievers were involved in over 16,200 of the nearly 44,000 drug overdose deaths in 2013.⁴ And these figures do not include deaths involving heroin, an illicit opioid that we are observing in increasing numbers.

Increased access to prescription painkillers in the past 15 years has corresponded with these substance use and medical consequences. The opioid drug abuse epidemic has grown proportionally with the tremendous increase in the prescribing of these medications since the mid-1990s. Therefore, two of the four pillars of the Administration's *Prescription Drug Abuse Prevention Plan (Plan)*⁵ – education and monitoring – focus on ways that prescribers more safely can provide opioid medications to their patients who legitimately need them to address their medical needs while avoiding prescribing these drugs for patients who may be using them non-medically or may not benefit from their use.

Managing patients' pain is a crucial area of clinical practice, but research indicates that health care practitioners receive little training on pain management, safe opioid prescribing, or recognizing and treating substance use disorders.^{6,7} Thus, one of the pillars of the *Plan* focuses on the need for prescribers to become better educated about appropriate prescribing practices. One of the action items in the *Plan* is requiring mandatory prescriber education connected to controlled substances licensure. The low response rates by prescribers to voluntary programs underscores the need for a mandatory education requirement on safer prescribing and substance use disorders, as has been adopted in at least eight states. We are gratified that some Members of Congress have proposed measures to enact mandatory prescriber education. We also note that efforts to train and educate health professionals on safe opioid prescribing, including the development of prescribing guidelines for chronic pain by the Centers for Disease Control and Prevention, is one of the three priority areas of the initiative announced by the Department of Health and Human Services (HHS) in March 2015 aimed at reducing opioid dependence and overdose.⁸

The *Plan*'s second pillar, monitoring, also addresses a way to transform prescriber practices to avoid the over-prescription or inappropriate prescribing of opioid drugs. Prescription Drug Monitoring Program (PDMP) data can help prescribers and pharmacists identify patients who may be at risk for substance use disorders, overdose, or other significant health consequences of

³ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: <http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2>

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Causes of Death, 1999-2013 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on January 30, 2015.

⁵ Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf

⁶ Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

⁷ U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: <http://www.gao.gov/assets/590/587301.pdf>

⁸ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. [March 2015]. Available: http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf

misusing prescription opioids. They also identify patients who may benefit from substance use disorder assessment and, if indicated, treatment. State regulatory and law enforcement agencies may also use this information to identify and prevent risky prescribing and possible diversion of controlled substances. Aggregate data from PDMPs can also be used to track the impact of policy changes on prescribing rates.

The third pillar of the *Plan*, proper medication disposal, addresses ways in which patients may become proactive in addressing this epidemic by providing means to dispose of unused, unneeded, or expired medications in a manner that will help prevent diversion and abuse and will help to reduce the introduction of drugs into the environment.

Action in these three areas will be helpful to address the opioid drug abuse epidemic, but we must be mindful of the continued need for the fourth pillar of the *Plan* – appropriate law enforcement – so that, like with all drug policy matters, we can approach this problem by addressing a public health concern while ensuring public safety. Our law enforcement partners have begun to adopt this balanced public health/public safety approach where practicable. For example, the law enforcement community has been receptive to equipping first responders with naloxone, an emergency opioid overdose reversal medication. Laws that provide criminal and/or civil liability protections to lay persons or first responders who administer naloxone enhance more widespread use, when needed, of naloxone. These actions to break the cycle of drug use, crime, and incarceration are transforming law enforcement as a partner in providing public health services, helping those with substance use disorders get the treatment that they need. Increasing access to naloxone is another priority area of the HHS opioid initiative.

As you correctly point out, we must take an approach to addressing the opioid drug abuse epidemic that balances the need to address the health concerns of both those who with legitimate need for pain medications and those with untreated substance use disorders with the need to support our law enforcement partners in their efforts to protect public safety.

The Honorable Michael Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

ANSWER:

In a Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs),¹ the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services proposed as a requirement for certification that electronic health records (EHRs) be capable of “streamlining access to PDMP [prescription drug monitoring program] data.” There was general support by the public for the proposed certification criteria; however, the Meaningful Use Workgroup of the Health IT Policy Committee (a Federal Advisory Committee), which was tasked with further exploring the inclusion of the PDMP criterion, ultimately decided that the technical standards to share information between an EHR system and a PDMP were not mature enough at the time to be required for certification.

In an effort to solve this interoperability challenge, ONC and HHS’s Substance Abuse and Mental Health Services Administration are leading work through the Standards and Interoperability (S&I) Framework’s PDMP/Health IT Integration initiative to examine the technical standards necessary to enable seamless data exchange between PDMPs and health IT systems (e.g., electronic health records, health information exchanges, and pharmacy systems).² PDMPs and health IT systems use different standards to communicate. This work harmonizes and maps the data elements of those standards to enable the information contained within the PDMP to be delivered directly to the hands of healthcare providers via their health IT systems, consequently solving the issue of having to log in to multiple systems and interrupting the clinical workflow to get the valuable PDMP data.

The S&I Framework, a collaborative community of participants from the public and private sectors focused on facilitating the functional exchange of health information, is pilot testing three standards (National Council for Prescription Drug Programs (NCPDP) 10.6; American Society for Automation in Pharmacy (ASAP) Web Services; and HL7 V2 messaging) that the S&I community agreed on. Currently, there are 5 active pilot teams testing the NCPDP 10.6 standard, with the anticipated deadline being late summer 2015. The ultimate timeline for the initiative is still being determined. Upon completion of NCPDP pilot testing, work will begin to pilot test the other standards, and a more precise timeline to achieve PDMP/Health IT integration will become clearer, as well as the necessary steps to facilitate this integration.

¹ http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf (Jan 2013)

² See <http://wiki.sifframework.org/PDMP%26%2BHealth%2B%2BIntegration%2BHomepage>

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

ANSWER:

Science demonstrates that the recent rise in opioid use disorders and the dramatic medical and social consequences we are seeing, including overdose, heroin use, injection drug use, and babies born exposed to opioids, all have roots in prescription opioid prescribing. It is essential for prescribing practices to change. While it is important to pursue all the action items in the Administration's *Prescription Drug Abuse Prevention Plan*, the single most important thing we can do is institute a mandatory requirement for the existing prescriber workforce to undergo training on safe opioid prescribing and substance use disorders. ONDCP is working with the Federal partners to determine the best approach to instituting mandatory prescriber education.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Minority (202) 235-3641

May 21, 2015

Dr. Richard G. Frank
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Frank:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

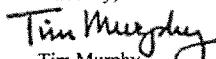
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Richard G. Frank, PhD
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services

Responses to Questions for the Record

House Energy and Commerce Subcommittee on
Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

May 1, 2015

I. Additional Questions for the Record

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

Answer: In response to a Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs) (comment deadline January 14, 2013), the Health IT Policy Committee recommended, as a criteria for certification, that EHR systems be capable of “streamlined access to prescription drug monitoring programs (PDMP) data.”¹ There was general support by the public for the recommended certification criteria; however, the Health IT Policy Committee’s Meaningful Use Workgroup, which was tasked with further exploring the inclusion of the PDMP criterion, ultimately determined that the technical standards to share information between an EHR system and PDMP were not mature enough at the time to include this as a criteria for certification as part of the Health IT Certification Program.

PDMPs and health information technology (IT) systems (e.g., electronic health records, health information exchanges, and pharmacy systems) use different standards to communicate. In an effort to address this interoperability challenge, ONC and the

¹ Available at http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf.

Substance Abuse and Mental Health Services Administration (SAMHSA) are leading work through the Standards & Interoperability (S&I) Framework's PDMP/Health IT Integration initiative to examine the technical standards necessary to enable more fluid data exchange between PDMPs and health IT systems. This work will harmonize and map the data elements of those standards to enable the information contained within the PDMP to be delivered directly to the hands of healthcare providers via their health IT systems, without the need for providers to log in to different systems to obtain PDMP data, which interrupts the clinical workflow.

The S&I Framework is pilot-testing three standards (NCPDP 10.6, ASAP Web Services, HL7 V2 messaging) that the S&I community identified. Currently, there are five active pilot teams testing the NCPDP 10.6 standard with an anticipated deadline of late summer 2015. Upon completion of NCPDP pilot-testing, work will begin to pilot test the other standards. The FY 2016 President's Budget includes \$5.0 million to build on this work and further integrate health IT and PDMPs in support of the Department-wide effort to address opioid addiction.

2. HHS already held a 50-state summit on opioid abuse and will hold another summit this summer. Can you provide to my staff a copy of a report from the first summit?

Answer: A summary on the 2014 50 State Working Meeting to Prevent Opioid-Related Overdose is under development. HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) will circulate the final report to the members of this Committee and make it available to the public on the ASPE webpage.

3. I have previously expressed my support for expanding access to naloxone. Potential solutions that have been raised include Good Samaritan laws and allowing for over the counter access to this treatment. Based off your experience, do you foresee any unintended consequences associated with increasing access to naloxone? What are the challenges?

Answer: Naloxone is a clinically-effective and cost-effective intervention that has been attributed to the prevention of over 10,000 overdose deaths since its introduction to the public through community-based programs in 1996. Increasing access to and use of naloxone, by both emergency personnel and at-risk individuals' associates, is critical to reducing overdose death. Studies to date have not shown any association between access to naloxone and increased drug use by naloxone recipients.² Lack of awareness about the effectiveness of this medication and policies that would limit the use of naloxone by first

² Bazazi A, Zaller N, Fu J, Rich J. Preventing opiate overdose deaths: examining objections to take-home naloxone. J Health Care Poor Underserved. 2010 Nov; 21(4): 1108-1113.

responders and overdose witnesses are barriers that we can overcome through improved research, education and implementation.

HHS is committed to identifying and disseminating best practice naloxone delivery models and strategies. On May 13, 2015 a notice was published in the Federal Register formally announcing a meeting on naloxone uptake and use, held by the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in collaboration with the National Institutes of Drug Abuse (NIDA), the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Health Resources and Services Administration (HRSA). This public meeting will be held July 1-2, 2015. The purpose of the public meeting is to explore issues surrounding the uptake of naloxone to treat opioid drug overdose. The meeting agenda will include topics on the clinical, regulatory, and legal implications of making naloxone more widely available. During the meeting, academic and government experts, industry representatives, and patient advocates will discuss which populations are at risk for opioid drug overdose and how the federal government can collaborate with these partners to encourage the use of naloxone to reduce the risk of overdose from opioid drugs.

- a. **There are also different naloxone products. Some require needles, while some are made into kits and can be used nasally. However there are potential down sides to each. Intravenous administration allows for potential exposure to blood borne pathogens to the administrator. Intranasal administration may decrease uptake of naloxone during an overdose, when every second counts. Can you talk about appropriate settings to incentivize each of these products?**

Answer: The development of user-friendly naloxone delivery devices is essential to our strategy to expand utilization of naloxone. Currently, naloxone is typically administered intravenously or intranasally. Last year, the FDA approved Evzio, a new naloxone drug product that is administered with an auto-injector. The National Institute on Drug Abuse (NIDA) and FDA are working collaboratively with the pharmaceutical industry to rapidly develop additional user-friendly naloxone delivery models that could be appropriate for use in a variety of settings.

II. Member Requests for the Record

The Honorable Tim Murphy

1. Please provide the committee with any federal legislative proposals that the Secretary has that would help combat this opioid epidemic and turn ideas into implementation.

Answer: The FY 2016 President's Budget lays out critical proposed investments to help combat the growing problem of opioid addiction throughout the country. For the Department of Health and Human Services, the budget proposes an increase of \$99 million above FY 2015 for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders, which includes both prescription opioids and heroin. HHS looks forward to working with the Committee on further developing these ideas.

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

The causes of the current opioid use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for HHS and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three-part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and

- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

There are many contributors to the Secretary's initiative and effective efforts are already in play in communities across the nation.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-2927
Minority (202) 225-3941

May 21, 2015

Dr. Nora D. Volkow
Director
National Institute on Drug Abuse
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Volkow:

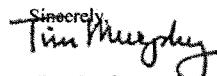
Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Thursday, June 4, 2015. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Dr. Nora Volkov, M.D.
National Institute on Drug Abuse
National Institutes of Health
Department of Health and Human Services

Responses to Questions for the Record

House Energy and Commerce Subcommittee on
Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

May 1, 2015

I. Additional Questions for the Record

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether HER certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

Answer: I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

2. Some have raised questions about the efficacy of medication assisted treatment. Can you please comment on what the standard of care is for treating individuals with opioid dependence?

Answer: The standard of care for treating individuals with opioid dependence includes treatment with medication in combination with psychosocial supports. The evidence strongly demonstrates that methadone, buprenorphine, and injectable naltrexone (e.g., Vivitrol), when administered in the context of an addiction treatment program, all effectively help maintain abstinence from other opioids, reduce opioid use disorder-related symptoms, and reduce the risk of infectious disease and crime. Two comprehensive Cochrane reviews, a process that statistically combines data from multiple studies, one analyzing data from 11 randomized clinical trials that compared the effectiveness of methadone to placebo and another analyzing data from 31 trials comparing buprenorphine or methadone treatment to placebo, found that:

- Patients on methadone were over four times more likely to stay in treatment and had 33 percent fewer opioid-positive drug tests compared to patients treated with placebo;¹
- Long-term (beyond six months) outcomes are better for patients receiving methadone when compared to patients treated with placebo, independent of counseling received;¹
- Buprenorphine treatment significantly decreased the number of opioid-positive drug tests when compared to patients treated with placebo, with some studies finding up to a 75-80 percent reduction in opioid positive drug tests;²

Broadly, the *Standards of Care for the Addiction Specialist Physician*, released by the American Society for Addiction Medicine (ASAM) in 2014, include comprehensive assessment and diagnosis, withdrawal management, treatment planning, treatment management, care transitions and care coordination, and continuing care management³. In the case of opioid use disorders, physicians should discuss and offer evidence based pharmacological therapies to all patients. To be clear, the evidence supports long term maintenance with these medicines in the context of behavioral treatment and recovery support, not short term detoxification programs aimed at abstinence from drugs of abuse. As stated in the Standards of Care:

“Maintenance treatments of addiction are associated with the development of a pharmacological steady-state in which receptors for addictive substances are occupied, resulting in relative or complete blockade of central nervous system receptors such that addictive substances are no longer sought for reward and/or relief....Integration of pharmacotherapy via maintenance treatments with psychosocial treatments generally is associated with the best clinical results.”³

Abstinence from all medicines may be a particular patient’s goal and that goal should be discussed between patients and providers. However the scientific evidence suggests the relapse rates are high when tapering off of these medications and abstinence orientations popular in many treatment programs do not facilitate patients’ long term, stable recovery.

¹ Mattick, R. P., Breen, C., Kimber, J. & Davoli, M. in *Cochrane Database of Systematic Reviews* (ed. The Cochrane Collaboration) (John Wiley & Sons, Ltd, 2009), at <http://doi.wiley.com/10.1002/14651858.CD002209.pub2>

² Mattick, R. P., Breen, C., Kimber, J. & Davoli, M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst. Rev.* **2**, CD002207 (2014).

³ American Society of Addiction Medicine (ASAM). The ASAM Standards of Care for the Addiction Specialist Physician. (2014), at <http://www.asam.org/docs/default-source/practice-support/quality-improvement/asam-standards-of-care.pdf?sfvrsn=10>

The Honorable Larry Buschon

1. What are the implications of most opioid-dependent patients not getting treatment in programs that use medication?

Answer: As treatment plans that incorporate medication are the standard of care for opioid use disorder (OUD), patients in programs without access to medications are not being treated with the best-available evidence-based treatments for addiction (see our response to Rep. Burgess' second question). A treatment plan that includes medication has the highest probability for being effective,⁴ yet only around 13 percent of all clients in treatment for OUD receive any of the three FDA-approved medications for this purpose.⁵ Even for patients who have access to programs offering medications,⁶ preauthorization and other administrative requirements can prevent timely care.⁶

Methadone, buprenorphine, and naltrexone have all been FDA-approved for treatment of OUD, which means that they have demonstrated clinically and statistically significant effectiveness.³ These medications improve a wide variety of outcomes; they increase retention in treatment and social functioning, while reducing opioid use, criminal activity, risk of HIV infection and risk of overdose. These benefits are seen in comparison to psychosocial therapeutic approaches that do not incorporate pharmacotherapies. A clinical trial comparing buprenorphine plus psychosocial treatment to psychosocial treatment alone found that none of the patients receiving psychosocial treatment alone were retained in treatment after two months, whereas 75 percent of patients in the buprenorphine group were retained in treatment for a full year and showed a 75-percent reduction in positive urine screens for other opioids. Of patients not retained in treatment, there was a 20 percent mortality rate.⁷ Outcomes are similarly improved in patients receiving methadone independent of counseling provided.^{7,8,9}

One implication of restricted access to MAT can be seen in studies that compare deaths due to opioid overdose before and after regional policy changes that expand access to MAT. Expansion of patients receiving MAT in Baltimore County was associated with a 66 percent reduction in heroin overdose deaths.¹⁰ While direct causation cannot be determined from this type of study, the results align with evidence from clinical studies to suggest that patients without access to MAT have poorer treatment outcomes.

⁴ National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction. Effective Medical Treatment of Opiate Addiction. *JAMA J. Am. Med. Assoc.* **280**, 1936–1943 (1998).

⁵ Knudsen, H. K., Abraham, A. J. & Roman, P. M. Adoption and implementation of medications in addiction treatment programs. *J. Addict. Med.* **5**, 21–27 (2011).

⁶ The American Society of Addiction Medicine. Advancing Access to Addiction Medications. (2013). at <http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.pdf>

⁷ Kakko, J., Svanborg, K. D., Kreek, M. J. & Heilig, M. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trial. *The Lancet* **361**, 662–668 (2003).

⁸ Schwartz, R. P. et al. A randomized controlled trial of interim methadone maintenance. *Arch. Gen. Psychiatry* **63**, 102–109 (2006).

⁹ Kinlock, T. W. et al. A randomized clinical trial of methadone maintenance for prisoners: results at 1-month post-release. *Drug Alcohol Depend.* **91**, 220–227 (2007).

¹⁰ Schwartz, R. P. et al. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995–2009. *Am. J. Public Health* **103**, 917–922 (2013).

2. I noticed the draft NIH National Pain Strategy did not mention technologies like SCS. What is NIH doing to promote FDA approved, non-pharmaceutical chronic pain treatments?

Answer: Chronic pain affects more than 100 million people in the United States and costs up to \$635 billion per year in medical treatment and lost productivity and contributing to poor quality of life.¹¹ Although opioid medications have a legitimate role in the treatment of acute pain and some chronic pain conditions, it is clear that they often are overprescribed or are prescribed without adequate safeguards and monitoring and that their misuse can have devastating effects. The development of more effective treatment interventions with lower risks is a significant research priority for NIH. The NIH spends over \$400 million annually to support chronic pain research ranging from basic science studies to understand the causes of chronic pain, to translational studies to develop novel treatments and clinical studies to determine optimal pain management approaches.

Spinal cord stimulation (SCS), is approved by the FDA for management of intractable chronic pain. It can be an effective non-pharmacological treatment option for some forms of chronic pain including complex regional pain syndrome. However, SCS is more invasive than other treatment options and is associated with risks for complications including leakage of cerebrospinal fluid, damage to nerves that come out of the spine, infection, nerve injury, etc. While these risks may be acceptable for some patients with severe chronic pain this may not be an ideal treatment option for many patients. In addition, 25-50 percent of patients report a loss of analgesia (pain relief) within 12-24 months of implantation.^{12,13} More larger scale research studies are needed to determine which patients are most likely to experience long term benefit from SCS. In the shorter term, however, it is important that all providers who treat chronic pain are educated on current evidence based treatment options for chronic pain including SCS and other non-pharmacological treatments.

One role of NIH is to fund research to determine whether an approach/device, which has already been shown to be safe for other conditions, is efficacious for pain management in particular settings. Several brain stimulation devices that are non-invasive (e.g., Transcranial Direct Current Stimulation, Transcutaneous Magnetic Stimulation, ultrasound, and combinations thereof) as well as a plethora of electrical stimulation devices for peripheral nerves/tissues have been cleared by FDA, but are not specifically indicated for pain management. NIH supports research on the effectiveness of these devices for use in treating chronic pain.

In addition, NIH also supports clinical trials to assess the use of natural products, as well as “mind and body” interventions such as mindfulness approaches, yoga, etc., for pain

¹¹ Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington (DC): National Academies Press (US); 2011. ISBN-13: 978-0-309-21484-1.

¹² Doleys DM. Neurosurg Focus. Psychological factors in spinal cord stimulation therapy: brief review and discussion. 2006 Dec 15;21(6):E1.

¹³ Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: 20 year literature review. J Neurosurg 2004; 100:254-267.

management, and some of these products require FDA clearance.

3. How do we increase patient access to these advanced non-opioid treatments?

Answer: NIH is not only focused on the development of next-generation pain treatment modalities, but also their effective dissemination and implementation so they reach patients who can benefit from them. Educating clinicians and clinicians-in-training regarding the most effective treatment modalities for pain is a critical element of this objective. In an effort to coordinate research on pain, and enhance clinician education, NIH established the NIH Pain Consortium, a collaboration of 25 NIH Institutes, Centers and Offices which coordinates collaborative pain research initiatives activities at NIH. The Consortium is funding the development of the first open-access chronic pain data registry to help identify pain management interventions that are most effective for specific patient-types with chronic pain. In addition, NIDA is leading an NIH Pain Consortium initiative to enhance pain education among physicians, nurses, and other health care providers. The Consortium currently supports 12 Centers for Excellence for Pain Education (CoEPEs) that act as hubs for the development, evaluation and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools. The curriculum resources developed by this program not only teach medications to treat specific pain conditions and factors that contribute to both under- and over-prescribing of pain medications, but also the latest research in complementary and integrative pain management options.

The National Pain Strategy, developed by the Interagency Pain Research Coordinating Committee and the NIH, on behalf of HHS, calls for a patient centered approach to pain management, which includes multidisciplinary, multimodal, and integrated care. Such an approach includes non-pharmacological interventions. Several recommendations in the strategy support the implementation of means to achieve this type of care.

The Honorable Jan Schakowsky

1. **The current standard of care for treating pregnant women with opioid dependence, according to the American College of Obstetricians and Gynecologists, is medication assisted therapy, such as buprenorphine or methadone. Medically supervised tapered doses of opioids or abrupt discontinuation are contrary to the current standard of care and are only appropriate in a highly controlled research setting.**

Can you tell us more about the standard of care for treating these patients?

Answer: The standard of care for treating pregnant women with opioid use disorder (OUD) involves use of the medications methadone or buprenorphine in combination with psychosocial support and prenatal care. Untreated OUD during pregnancy can have devastating effects on the fetus. The fluctuating levels of opioids in the blood of mothers with opioid use disorder expose the fetus to repeated periods of *in utero* withdrawal¹⁴, and can result in restricted growth, preterm labor, convulsions, and

¹⁴ Kaltenbach, K., Berghella, V. & Finnegan, L. Opioid dependence during pregnancy. Effects and management. *Obstet. Gynecol. Clin. North Am.* **25**, 139–151 (1998).

even in the death of the fetus. In addition to these direct physical effects, untreated OUD is also associated with increased risk of complications from untreated maternal infections, such as HIV,¹⁵ malnutrition and poor prenatal care,¹⁶ and dangers conferred by active use of illicit drugs and non-medical use of prescription drugs, including violence and incarceration.^{14, 17}

To mitigate the negative effects of OUD on the fetus, treatment with methadone has been used for pregnant women with OUD since the 1970s, and has been recognized as the standard of care since 1998. Official statements from the National Institutes of Health National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction,¹³ along with The American College of Obstetricians and Gynecologists and the American Society of Addiction Medicine,¹⁵ document methadone treatment as best practice for opioid use disorder in pregnancy. The Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Improvement Protocols (TIP 40, 43) indicate that methadone and buprenorphine treatment stabilizes fetal levels of opioids, reducing repeated prenatal withdrawal^{12, 18} increases maternal HIV treatment to reduce the likelihood of transmittal to the fetus,^{13, 15} and links mothers to better prenatal care,^{14, 15} Even though neonatal abstinence syndrome (NAS) may occur in babies whose mothers have received MAT, it is less severe than it would be in the absence of treatment.

Both methadone and buprenorphine reduce the incidence and severity of NAS, resulting in a shorter treatment time for the baby.^{19, 20} However, recent evidence suggests Buprenorphine may be a better treatment option for opioid use disorders in pregnant women. Comparing buprenorphine to methadone treatment (in a meta-analysis),¹⁸ buprenorphine treatment resulted in:

- 10 percent lower incidence of NAS
- shorter treatment time (an average of 8.46 days shorter)
- lower amount of morphine used for NAS treatment (an average of 3.6mg lower)
- higher gestational age, weight and head circumference at birth.

¹⁵ National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction. Effective Medical Treatment of Opiate Addiction. *JAMA J. Am. Med. Assoc.* **280**, 1936–1943 (1998).

¹⁶ Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series 43. (2005). at <<http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf>>

¹⁷ The American College of Obstetricians and Gynecologists & The American Society of Addiction Medicine. Opioid Abuse, Dependence and Addiction in Pregnancy. (2012). at <<http://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co524.pdf?dmc=1&ts=20150429T1228129639>>

¹⁸ Kandall, S. R., Doberczak, T. M., Jantunen, M. & Stein, J. The methadone-maintained pregnancy. *Clin. Perinatol.* **26**, 173–183 (1999).

¹⁹ Fajemirokun-Odudeyi, O. *et al.* Pregnancy outcome in women who use opiates. *Eur. J. Obstet. Gynecol. Reprod. Biol.* **126**, 170–175 (2006).

²⁰ Brogly, S. B., Saia, K. A., Walley, A. Y., Du, H. M. & Sebastiani, P. Prenatal buprenorphine versus methadone exposure and neonatal outcomes: systematic review and meta-analysis. *Am. J. Epidemiol.* **180**, 673–686 (2014).

II. Member Requests for the Record

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

The causes of the current opioid use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for HHS and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and
- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measurable impact.

NIDA's top priority in contributing to this coordinated HHS strategy is to improve the education of healthcare providers on evidence-based practices for treating pain. There is still much we don't know about the best methods for treating chronic pain, and NIDA is supporting significant ongoing research to better understand this issue. However, we do know that opioids are typically not the best treatment for chronic non-cancer pain, yet they are still frequently prescribed as a first line treatment in this context. The United States makes up only 4.6 percent of the world's population, but consumes 80 percent of

its opioids, resulting in disproportionately high rates of opioid use disorders and overdose deaths.

To improve the education of providers on evidence based strategies for addressing pain NIDA, in partnership with the NIH Pain Consortium, is helping to fund 12 Centers of Excellence in Pain Education that act as hubs for the development and dissemination of pain management curriculum resources for medical, dental, nursing and pharmacy schools to enhance and improve how health care professionals are taught about pain and its treatment. The FY 2016 President's Budget includes a proposal for continued funding for these centers of excellence, and we encourage the Congress to fully fund this program.

In addition, NIDA, in partnership with the Office of National Drug Control Policy, developed two online continuing medical education courses on safe prescribing for pain and managing patients who abuse prescription opioids. To date, these courses have been completed by over 100,000 clinicians combined. NIDA also strongly supports mandatory prescriber education in this area. Pain can be a component of nearly every medical issue and every provider should be well-trained in how to appropriately address pain while minimizing risk for negative outcomes including addiction and overdose.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

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COMMITTEE ON ENERGY AND COMMERCE

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May 21, 2015

Dr. Douglas Throckmorton
Deputy Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Throckmorton:

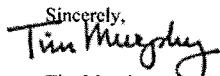
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

 Tim Murphy
 Chairman
 Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 08 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the May 1, 2015, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?" This letter is a response for the record to questions posed by certain Members of the Committee.

If you have further questions, please let us know.

Sincerely,

for

Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Diana DeGette
Ranking Member

Page 2 - The Honorable Tim Murphy

We have restated each Member's questions below in bold, followed by our responses.

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

The Honorable Larry Buchson

1. **Can you expand a bit on your experience with Vivitrol (aka naltrexone) specifically, and how greater access could be helpful across the nation?**

Vivitrol is an extended-release formulation of naltrexone administered by intramuscular injection once a month. Naltrexone works to block opioid receptors in the brain. It blocks the effects of drugs like morphine, heroin, and other opioids. It was approved in October 2010 for the prevention of relapse to opioid dependence, following opioid detoxification, in patients addicted to opioid drugs.

An oral formulation of naltrexone, under the trade name Trexan, was approved in 1984 for its effect in blocking exogenous opioids, which was intended to support formerly opioid-dependent patients in maintaining a drug-free state. Although its pharmacologic properties are well-established, and its theoretical benefit in preventing relapse to illicit opioid use in detoxified patients is accepted, it was challenging to show that those properties translate into effective relapse prevention in the clinical setting for this oral form of naloxone, perhaps due to poor compliance. Therefore, the development of passive-compliance formulations such as implants, transdermals, and depot injections was a logical extension in the development of naltrexone for treating substance use disorder, and Vivitrol was developed with this in mind.

The safety and efficacy of Vivitrol were studied for six months, comparing Vivitrol injections every four weeks to placebo treatment in patients who had completed inpatient detoxification and who were no longer physically dependent on opioids. Patients were seen weekly for behavioral treatment and provided weekly urine samples for toxicology testing, and also provided self-reports on their illicit drug use. Although many patients did use drugs on some occasions, 36 percent of the Vivitrol-treated patients were able to stay in

Page 3 - The Honorable Tim Murphy

treatment for the full six months without using drugs, compared to 23% in the placebo group.

This built upon evidence from a clinical pharmacology study showing that Vivitrol blocked the effects of opioids for a full month, and demonstrated that this blockade translated into clinical benefit by preventing relapses and keeping patients in treatment.

Given these data, Vivitrol represents an important addition to the pharmacologic treatment armamentarium for patients motivated to stay opioid-free after detoxification, which also includes oral naltrexone and the opioid agonist methadone and buprenorphine. Given the complexity of treating substance use disorder, these should all be used as a part of a larger treatment program, including non-pharmacologic and behavioral treatment options.

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

The causes of the current opioid-use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for the Department of Health and Human Services (HHS or the Department) and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three-part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and
- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

Page 4 - The Honorable Tim Murphy

These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measurable impact. FDA is working to support these goals where possible.

With regard to assuring that prescribers receive effective training on the safe uses of opioid drugs, the Secretary's initiative includes support for mandatory prescriber education on responsible opioid prescribing practices. As called for by the Administration in the 2011 Prescription Drug Abuse Prevention Plan, and re-emphasized in the 2014 National Drug Control Strategy, mandatory prescriber education is a critical component of the response to the opioid epidemic.

A first step in providing education to providers was taken by FDA through its Risk Evaluation and Mitigation Strategy for Extended-Release/Long-Acting (ER/LA) opioid analgesic products (ER/LA opioid analgesic REMS). The REMS, approved in July 2012, requires manufacturers of ER/LA opioid analgesics to make education programs available to all prescribers of ER/LA opioid analgesics, by providing educational grants to accredited continuing education (CE) providers, who, in turn, offer training to prescribers at little to no cost. These CE activities must cover the content and messages of an education blueprint developed by FDA. Although this training is an important public health measure, FDA continues to support mandatory education for prescribers. By providing effective training, we can help prescribers make better decisions about which patients will benefit from the use of opioids, and when patients could be harmed by them or could benefit from other ways to manage their pain.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

May 21, 2015

Dr. Debra Houry
Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Houry:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy
Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Dr. Debra Houry, M.D.
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Department of Health and Human Services

Responses to Questions for the Record

House Energy and Commerce Subcommittee on
Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

May 1, 2015

I. Additional Questions for the Record

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

Answer: I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

2. Complaints regarding PDMPs suggest that these systems are not real time, not widely used, and are time consuming and burdensome. In 2005, Congress enacted NASPER, with strong support from health care providers and broad, bipartisan support. NASPER could explicitly address both of these programs. However, the program has not been funded since 2010 and faced similar lack of funding prior to 2010. NASPER would provide assistance to allow PDMPs to meet consistent national criteria and allow for interoperability between state PDMPs. Do you think that national criteria and standardized content would be beneficial in fostering a more attractive state-based PDMP network for providers?

Answer: Prescription Drug Monitoring Programs (PDMPs) face the traditional struggle of creating a level of uniformity among states for national consistency and efficiency purposes while allowing individual states to address their unique policy direction and state laws. Encouraging states to implement identified best practices such as interstate data sharing and interoperability with health information technology (IT) may foster a more attractive PDMP network for providers thereby increasing PDMP utilization.

In an effort to streamline access to PDMP data so that it is available quickly and easily within the clinical workflow, the Office of the National Coordinator (ONC) Standards & Interoperability (S&I) Framework's PDMP/Health IT Integration Initiative was launched as part of the "Enhancing Access to PDMPs using Health IT" project (a joint effort between ONC, the Substance Abuse and Mental Health Services Administration (SAMHSA), The Centers for Disease Control and Prevention (CDC) and the Office of National Drug Control Policy (ONDCP)) to bring together the PDMP and health IT communities to evaluate data format standards for exchanging information between PDMP and provider health IT systems.¹

With respect to content, most states already list in their PDMP statutes and regulations a set of data that is required for collection, with the PDMP Administrator having discretion to include additional data. From a healthcare perspective, we have heard from stakeholders that the key is identifying those pieces of information deemed important to clinical decision-making and ensuring that the data is provided to the health care professional end-user. The collection of a minimum set of data across states and more harmonized state policies could enable a more standardized technical solution.

a. What has been your experience with interstate accessibility of PDMPs? Are the current interstate data-sharing exchanges, such as Prescription Drug Monitoring Program Interconnect effective?

Answer: Since the beginning of the Administration, we made significant progress with respect to interstate data sharing. Current interstate data-sharing exchanges, such as National Association of Boards of Pharmacy's PMP InterConnect, enable the transfer of PDMP data across state lines to authorized users while adhering to the state's data-access rules. Twenty-nine states are currently sharing data through PMP InterConnect. PMP InterConnect allows participating PDMPs across the country to be linked, which can provide a more effective means of combating drug diversion and drug abuse nationwide. This data-sharing exchange enables a practitioner, pharmacist, or other authorized user to obtain multistate PDMP data, which gives the healthcare provider a fuller picture of a patient's controlled

¹ Additional information available at <http://www.healthit.gov/PDMP>.

substance prescription history. This information also helps providers to better identify patients with prescription drug abuse problems, especially if those patients are crossing state lines to obtain controlled substance prescriptions.

II. Member Requests for the Record**The Honorable David McKinley****1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?**

Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

The causes of the current opioid use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for HHS and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three-part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and
- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measureable impact.

As the nation's public health agency, CDC's core role in this epidemic is furthering the first part of the HHS initiative: Providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions and address the over-prescribing of opioids. Changes in the prescribing of opioid pain relievers contributed to and continue to drive the epidemic. Aligning safe and clinically appropriate prescribing to better reflect the risks and benefits of opioids would have a major impact by reducing opioid overprescribing, misuse, and overdose, ultimately protecting patients.

Improving opioid prescribing is complex as there are many different levers that affect this clinical practice. States, public and private payers, health systems, healthcare providers, and patients all play a role in improving opioid prescribing. CDC's aim is to advance this goal through several key programs and activities.

First, CDC is developing new opioid prescribing guidelines for chronic pain outside of the end-of-life setting. CDC is convening an expert group to inform the guideline development and plans to release the new guidelines in FY 2016. These guidelines will serve as a foundation to guide states, insurers, health systems, and providers on prescribing best practices. In addition to the development and release of the guidelines, broad dissemination and uptake among providers are crucial, and both are additional activities CDC is working to accomplish in FY 2016.

Second, CDC is supporting states through its *Prevention for States* program to provide direct support to advance promising strategies for improving prescribing and reducing overdose deaths. Building on lessons learned through its Prescription Drug Overdose: Boost for State Prevention program, which began in FY 2014 and funds five states, CDC launched *Prevention for States* in FY 2015 and anticipates funding approximately 16 states to conduct the following activities:

- Enhancing PDMPs (*i.e.*, real-time, proactive reporting) as a public health surveillance and clinical decision making tool;
- Implementing community-level and health system interventions such as patient review and restriction programs that limit high risk patients to one doctor and one pharmacy for their opioids;
- Evaluating prevention policies for effectiveness like those states passing pill mill or doctor shopping laws; and
- Advancing rapid response projects to afford states the flexibility and resources to respond to new and emerging problems.

If funded by the Congress at the level proposed in the FY 2016 President's Budget, CDC would be equipped to scale up its state-based program for a truly national response to the prescription drug overdose epidemic. CDC would fund all 50 states and Washington, D.C., to support the advancement of promising prevention on multiple fronts to improve prescribing practices nationwide, in support of and in alignment with the Department's initiative.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

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May 21, 2015

The Honorable Pamela S. Hyde
Administrator
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Dear Ms. Hyde:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

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cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Pamela S. Hyde, J.D., Administrator,
Substance Abuse and Mental Health Services Administration

Responses to Questions for the Record

House Committee on Energy and Commerce Subcommittee on
Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid
Abuse Epidemic?”
May 1, 2015

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a POMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

Answer: I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

The Honorable Jan Schakowsky

1. There are currently significant barriers to accessing treatment for pregnant and postpartum women with opioid dependence. For pregnant women, in-patient treatment is not always appropriate, as these women may have full-time jobs or be the primary caregiver for their other children -- situations that don't allow them to put their lives on hold to enter an inpatient facility. In addition, many facilities don't allow or can't accommodate women with young children. For postpartum women, Medicaid coverage for pregnancy expires 6 weeks postpartum. That means that young mothers may lose access to buprenorphine or methadone soon after giving birth, when stability is needed most.

How can we ensure that pregnant and postpartum women have better access to treatment options that work for them -- like outpatient treatment -- and ensure that they do not lose access to their maintenance medications shortly after giving birth?

Answer: SAMHSA agrees that residential treatment is not a one-size-fits-all approach and that pregnant women with substance use disorders should have access to a range of evidence-based treatment models across the spectrum of care.

In order to bolster the availability of family-based residential treatment options when they are needed, SAMHSA administers the Pregnant and Postpartum Women Program (PPW), which is a grant program that provides residential treatment services for pregnant and postpartum women with substance use and/or co-occurring substance use and mental disorders and their minor children. The program was last reauthorized in the Children's Health Act of 2000 and the statute specifies that the program is for residential treatment. SAMHSA agrees that pregnant and postpartum women need better access to treatment options that work for them, such as outpatient treatment.

From FY 2003 to FY 2014, SAMHSA funded 101 three-year PPW grants. In FY 2015, SAMHSA anticipates funding up to six additional, three-year PPW grants.

SAMHSA added new reporting requirements to the 2016-2017 Behavioral Health Assessment and Plan for pregnant women and women with dependent children, which will help track and improve the care for women with opioid use disorder after discharge from residential treatment. The new reporting requirements include information on strategies to ensure treatment availability; details on how states ensure that pregnant women are admitted to treatment within 48 hours or provided interim treatment services if no treatment facility is readily available; and specific program data, including geographic areas that cannot provide adequate care (including medication-assisted treatment (MAT)). SAMHSA expects that states will use this information to improve the planning of care for opioid dependent pregnant women, across all levels of care, from hospital-based, to residential, intensive outpatient, and outpatient treatment.

SAMHSA also manages the Substance Abuse Prevention and Treatment Block Grant (SABG), which includes a requirement that states expend a percentage of their annual SABG allotment on services specifically for pregnant women and women with dependent children. The women's set-aside is a performance requirement that allows states the flexibility to expend a combination of federal and non-federal funds to support residential or outpatient treatment services for pregnant women and women with dependent children. In 2014, more than 28,000 pregnant women received services through the set-aside.

The Centers for Medicare & Medicaid Services (CMS) remains committed to making sure women have access to needed medications. A life change such as having a baby qualifies a woman for a special enrollment period for coverage in the Health Insurance Marketplaces. The special enrollment period enables an eligible woman who recently gave birth to enroll in health insurance and receive tax subsidies outside of the annual open enrollment period if she qualifies.

In states that have expanded Medicaid coverage as outlined in the Affordable Care Act, many individuals, including new mothers, have increased access to coverage. Expanding Medicaid is a good deal for states financially. The Federal Government will cover 100 percent of the cost of covering people made newly eligible for Medicaid for the first three years (2014-2016). The Federal Government will cover no less than 90 percent on a

permanent basis. This is the most generous matching rate applied to any coverage group in the history of the program.

Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Tim Murphy

1. During the hearing I asked you about your response to our March 18 letter, specifically regarding NREPP and evidence-based programs. Please provide the committee with a list of what you consider to be some of the models of evidence-based programs within the Federal registry.

Answer: The National Registry of Evidence-based Programs and Practices (NREPP) includes several well-established and well-known programs. It is worth noting that NREPP has been built exclusively through voluntary submissions by program developers. Given this approach, not every well-known and established evidence-based practice has been reviewed or captured by NREPP. As detailed in our response to your March 18 letter, in the future, developers will still have the option of submitting their programs for review, but SAMHSA will also conduct independent literature searches in an effort to identify a broad swath of evidence-based programs and practices that otherwise might not be submitted to NREPP.

NREPP contains programs that seek to improve a person's adherence to their medication regimen while addressing other critical issues, such as coordinated care with physical health co-morbidities. These include, but are not limited to:

- Interim Methadone Maintenance¹
- Motivation Enhancement Therapy²
- Dialectical Behavioral Therapy³

On the current registry, there is also a family of programs that use cognitive behavioral therapy, including but not limited to:

- Cognitive Behavioral Intervention for Trauma in Schools;
- Cognitive Behavioral Therapy for Adolescent Depression;
- Cognitive Behavioral Therapy for Late-life Depression; and,
- Cognitive Processing Therapy for Posttraumatic Stress Disorder.

Cognitive behavioral therapy is often used in conjunction with other modalities, including medication, to address issues related to psychoses and other serious mental illnesses and has a significant evidence base to support its use with multiple target populations and a range of behavioral health issues.

¹ Available at <http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=19>.

² Available at <http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=347>.

³ Available at <http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=36>.

2. During the hearing I was following up on a question I asked you in a previous hearing regarding the Building Blocks website. You indicated that the website had been taken down and you were in the process of updating it. Please provide the committee with process reports.

Answer: On March 19, 2015, the Building Blocks website was taken down and a message posted that the site is temporarily unavailable.

SAMHSA's Center for Substance Abuse Prevention (CSAP) worked with the National Institute on Drug Abuse (NIDA) regarding ways to strengthen the evidence base for substance use disorder prevention content on the website.

SAMHSA is scheduled to re-launch the Building Blocks website with revised content this summer.

3. You mentioned at the hearing that SAMHSA has been rethinking the 42 CFR part 2 rules, and that last year you held a listening session for stakeholders and took those pieces of input, and are trying to balance privacy concerns with the need for access to data. Can you please let the committee know as soon as you have something available for public input addressing these issues?

Answer: SAMHSA held a public listening session in June 2014 to solicit input from the public on potential updates to the 42 CFR Part 2 regulation. SAMHSA invited general comments, as well as comments on six key provisions of 42 CFR Part 2: Applicability, Consent Requirements, Re-disclosure, Medical Emergency, Qualified Service Organization, and Research. In addition, SAMHSA solicited input on electronic prescribing and Prescription Drug Monitoring Programs, areas that could potentially impact Part 2 programs. About 1,800 individuals participated in the listening session, either in person or by phone, and over 700 comments were submitted.

In addition to considering the wealth of public input received, SAMHSA is collaborating with its Federal partners in drafting a Notice of Proposed Rulemaking (NPRM). SAMHSA would be pleased to brief the committee on NPRM as soon as it is published.

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

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factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

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These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measureable impact.

SAMHSA supports the Secretary's initiative to address opioid related overdose, death, and dependence through our programs and initiatives that address the three key areas of the Department's initiative: opioid prescribing practices, increasing use of naloxone, and expanding use of MAT.

As the rates of prescription drug misuse and abuse, heroin use, overdoses, and opioid-related overdose deaths increase, communities are searching for ways to reduce the mortality rate of opioid-related overdoses. The FY 2016 Budget for SAMHSA includes \$12 million for a new program which would provide grants to 10 states to purchase naloxone, equip and train first responders in high-risk communities on its use, support education on the use of naloxone and other overdose death prevention strategies, and support dissemination efforts.

These grantees would be required to develop an Opioid Overdose Prevention Toolkit dissemination plan and a training course tailored to meet the needs of their community. The course would use SAMHSA's Opioid Overdose Prevention Toolkit as a guide, and include a comprehensive prevention program which will focus on prevention, treatment and recovery services to decrease the likelihood of drug overdose recurrence. The Centers for Disease Control and Prevention (CDC) would evaluate this grant program for its efficacy in reducing overdose deaths from opioids.

By supporting this new program, the Congress can take an important step to advance SAMHSA's efforts to address the public health crisis related to opioid misuse and abuse.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

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May 21, 2015

Dr. Patrick Conway
Deputy Administrator for Innovation and Quality &
CMS Chief Medical Officer
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Conway:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, May 1, 2015, to testify at the hearing entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic."

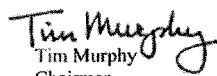
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Tim Murphy
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cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Dr. Patrick, M.D.
Deputy Administrator for Innovation and Quality & Chief Medical Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services

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I. Additional Questions for the Record

The Honorable Michael C. Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

Answer: I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

The Honorable Jan Schakowsky

1. A concern of mine is that women who have recently given birth, who have opioid dependence and have pregnancy coverage through Medicaid, will lose that coverage 6 weeks postpartum. This means that they may lose their access to their physician prescribed buprenorphine or methadone soon after giving birth, when stability is needed most.

How can CMS ensure that these new mothers do not lose access to their maintenance medications shortly after giving birth?

Answer: The Centers for Medicare & Medicaid Services (CMS) remains committed to making sure women have access to needed medications. CMS, in coordination with CDC, SAMSHA, and NIH, issued an informational bulletin on Medication Assisted Treatment (MAT) for Substance Use Disorders in the Medicaid program. This

informational bulletin provides background information about MAT, examples of state-based initiatives, and useful resources for states to help ensure proper delivery of these services.

A life change such as having a baby qualifies a woman for a special enrollment period for coverage in the Health Insurance Marketplaces. The special enrollment period enables an eligible woman who recently gave birth to enroll in health insurance and receive tax subsidies outside of the annual open enrollment period if she qualifies.

In states that have expanded Medicaid coverage as outlined in the Affordable Care Act, many individuals, including new mothers, have increased access to coverage. Expanding Medicaid is a good deal for states financially. The Federal Government will cover 100 percent of the cost of covering people made newly eligible for Medicaid for the first three years (2014-2016). The Federal Government will cover no less than 90 percent on a permanent basis. This is the most generous matching rate applied to any coverage group in the history of the program.

II. Member Requests for the Record

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

The causes of the current opioid use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for HHS and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three-part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and

- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measurable impact.

CMS is committed to ensuring that all Medicare and Medicaid beneficiaries are receiving the medicines they need while also reducing and preventing prescription drug abuse. For example, the FY 2016 President's Budget¹ includes a proposal to prevent prescription drug abuse in Medicare Part D that would give the Secretary of HHS the authority to establish a program that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to many State Medicaid programs. The Medicare program would be required to ensure that beneficiaries retain reasonable access to services of adequate quality. Currently, CMS requires Part D sponsors to conduct drug utilization reviews, which assess the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. However, CMS' statutory authority to take preventive measures in response to this information is limited. We urge the Congress to pass this proposal to provide CMS with this additional authority.

Addressing the opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.

¹ Fiscal Year 2016 Budget in Brief, <http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html>

